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Improving patient-centredness of fertility care

Dana Huppelschoten

All studies in this thesis were conducted at the department of Obstetrics and Gynaecology at the Radboud University Medical Centre, which is part of the Nijmegen Centre for Evidence Based Practice (NCEBP), one of the approved research institutes of the Radboud University Nijmegen.

For reasons of consistency, terminology may be changed throughout this thesis when compared to the original publications.

The studies in this thesis have been made possible by Merck Sharp and Dohme (MSD), the Netherlands.

Publication of this thesis was furthermore sponsored by:

Afdeling Verloskunde & Gynaecologie Radboudumc
Chipsoft
Ferring B.V.
Goodlife Fertility B.V.
Medical Dynamics
Merck Serono The Netherlands
Origio Benelux

Layout and cover design: Wilco Huppelschoten

Printed by: Offpage

ISBN: 978-94-6182-379-3

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Proefschrift

Ter verkrijging van de graad van doctor
aan de Radboud Universiteit Nijmegen
op gezag van de rector magnificus, prof. Mr. S.C.J.J. Kortmann,
volgens besluit van het College van Decanen
in het openbaar te verdedigen op
donderdag 23 januari 2014
om 12.30 uur precies

door

Aleida Gerarda Huppelschoten

geboren op 10 augustus 1984
te Amersfoort

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PROLOGUE

FERTILITY CARE THROUGH THE EYES OF A PATIENT

Fertility care through the eyes of a patient

"We will get you pregnant, lady!" These were literally the words a doctor once told me. 'We' were the all-knowing doctors who would make sure that I got what I wanted: a baby. Of course, this doctor could never make me this promise, as I already knew that the chance to achieve pregnancy was far from 100%. But more important, I did not appreciate the tone my doctor used, as it sounded like: "Please, do not think too much yourself, but just listen to me and follow my orders. I, 'Mr. Gynaecology', will make sure that it will all turn out well." Maybe his intentions were not so bad at all, but patient-centred? No, this was definitely not what I expected from a patient-centred approach.

Do I feel that it is important to provide patient-centred care? I can answer this question with a clear 'Yes!'. I can also support this with many true stories, which my husband and I experienced during the five years that we were under treatment for our unfulfilled desire to have children. During these years, we went through different positive and negative experiences that were quite demanding and stressful. To make it more understandable how it is to be a patient suffering from infertility, I will walk you through some of my experiences.

Can I make a new appointment?

After I had undergone a laparoscopy to figure out the cause of my fertility problem, my doctor told me to make a new appointment within two weeks to start up a new treatment cycle. The next day, when I called the secretary, she surprisingly answered: 'This must be a mistake, because it is absolutely not possible to make an appointment only two weeks after surgery. Obviously, your body needs more time to recover.' Of course, I was amazed and I tried to convince her that this was really what the doctor had told me. But before I could finish my sentence, she has already passed me through to her colleague. Again, she only confirmed what her colleague had just told me. Who should I believe? The doctor, who told me to return within two weeks to continue my treatment (and I had already started to take hormones for this new treatment), or the secretaries, who were also firm in their statements. I decided to call again the next morning. And guess what? Suddenly, it was no problem to see the doctor and there was nothing to worry about. However, the previous calls had already made me very insecure and had stressed me out, which obviously could have been prevented.

Big bellies

In the waiting room of my hospital, I often had to sit next to patients who were already pregnant. Most of these patients were happy women, all discussing the progress of their pregnancies together. That's good for them of course, but very

difficult for everyone who suffers from infertility. It was very hard for me to see all these big bellies while I wanted to have such a belly for myself. Once, my doctor asked me to return to the waiting room for a few more minutes, because he wanted to discuss his findings with a colleague. There I was, sitting next to a mother with a two-year old and obviously pregnant with her second child. Oh, I definitely wanted to put myself in her shoes and felt really miserable!

Different doctors, different stories

Communication between doctors... my experiences in this area are not really impressive. For example, it happened several times that a doctor asked me what he had to do during the appointment. Obviously, the doctor was not aware of the treatment plan my own doctor had composed and had not even read my medical record before I entered the room. Also the advice the doctors gave me was not always in line or even contradictory. It seemed like all doctors handled our fertility problem in their own way. That is strange, isn't it? It also scared me a little bit, as I already felt psychological pressure to deal with my fertility problem. Now I also had to take care that my doctors were all pointing in the same direction regarding my fertility treatments. A new doctor once told us that our own doctor should never have introduced the IVF treatment that quickly. According to him, we had several other valid treatment options. Very confusing, as we did not know who was right. Also, some discussion was raised when I suggested a new treatment I read about in a magazine. Our doctor told me that this treatment option was not even possible in our hospital, while exactly the opposite was true according to his colleague. It turned out that no previous patient had been eligible for this treatment before. Eventually, I was the first patient receiving that specific treatment in our clinic and because of the worse communication, my husband and I decided to go to another doctor!

Imagine it is about you

One day, when I needed another ultrasound check-up, a lot of small follicles were visible on the screen, which didn't seem good enough for an ovulation. This was a huge disappointment to me, but my doctor just said: 'You have seen this before right? Yes, your endometrial layer looks fine, but this is not what you need of course!' Well, that was just the last thing I wanted to hear, such a platitude!

Another example I would like to share, is about my admission to the hospital a few years ago. I was admitted because of blood loss during my pregnancy. Yes, we finally got pregnant and these periods with recurrent blood loss were very frightening and stressful to us. Therefore, it was even more striking that I heard a doctor speaking out loud to the nurse before he entered my room: 'It is very

nice and quiet on this section today. Watch me, I will make sure that it will be even more quiet.’ Then he entered my room and asked me how I was doing. I told him that my blood loss had stopped since that night. Then I was ‘allowed’ to go home, he said. He obviously thought that he did me a favor, but he did not even ask me what I wanted. Because of my history, I would have preferred to stay another day to be sure the blood loss had really stopped. In my opinion, this was a perfect example of ‘talking about the patient’, instead of ‘talking to the patient’.

Patient-centred care

Now it seems like we have only had negative experiences with fertility care, which is of course not true. During the five years of fertility treatments, we met a doctor who perfectly answered our expectations on how a doctor should be and he became our own doctor. What was so special about him? According to us, he was always there when we needed him and he took the time to answer all our questions. It was always possible to call him or to make an additional appointment, if we wanted to. We felt like we were not alone and were treated like human beings. This was very important to us, especially in these difficult and uncertain times.

The remark this prologue started with, was clearly not a sign of empathy. I hope that these examples of my personal experiences have illustrated what patients need when they are treated for their fertility problem. When discussing the content of patient-centred care, I think that the remark of the doctor should have been: *"Together, we will do everything that is in our power to fulfill your desire to have a child."* In this case, ‘we’ stands for the professional team and the patient together, and not the doctors, nurses or secretaries alone. In my opinion, *working together* is the heart of the matter when it comes to patient-centred care.

Ingrid van der Kuil

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This prologue was based on the book “Koningskinderen”

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ISBN 9789081954006

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CHAPTER 1

GENERAL INTRODUCTION

General Introduction

Story and reality: fertility care in the Netherlands

The patient you read about in the prologue was being treated in a Dutch fertility clinic, because she and her partner failed to achieve pregnancy after having at least one year of regular unprotected intercourse.¹ Unfortunately, they are not the only couple dealing with this problem, as infertility is estimated to affect about 80 million couples of the current global population.^{2,3} In developed countries, such as the Netherlands, one in six couples who have tried to achieve pregnancy suffers from infertility.^{4,5} Approximately 55% of these couples seek medical help and start with a diagnostic workup to determine the cause of their fertility problem and come to an appropriate treatment.^{3,6} In the majority of cases, male and/or female causes are found, such as low sperm counts and/or ovulation disorders.⁵ However, in about 8-28% of cases, the cause of infertility remains unknown.⁷

The effectiveness of the different treatment options in fertility care is limited. However, due to professionalization and standardization of care in recent years about 70% of the couples achieves pregnancy after one or more cycles of Medically Assisted Reproduction (MAR) nowadays.^{8,9} These treatments include ovulation induction (OI), intra-uterine insemination (IUI), *in vitro* fertilization (IVF), intra-cytoplasmic sperm injection (ICSI) and surgical sperm retrieval.¹⁰ In the Netherlands, initial fertility assessment, OI and IUI treatments are offered in all clinics, but only the intermediate Dutch clinics can also start up and monitor IVF and ICSI treatments (i.e. transport and satellite clinics). A total of thirteen Dutch clinics are licensed to perform the laboratory phase and embryo transfers of the IVF and ICSI treatments as well. This means that several patients have to visit more than one clinic during their treatment period, which is often lengthy. However, the presence of the smaller clinics, transport and satellite clinics makes Dutch fertility care accessible throughout the entire country. Nowadays, about 15.000 IVF and ICSI cycles are performed each year in Dutch clinics, resulting in 1 in 40 children who are born after fertility treatments involving *in vitro* techniques.¹¹

Financial coverage of all these treatments is mainly organized by public funding in which Dutch health insurers have a prominent role. After negotiating about prices and quality, they arrange contracts with different healthcare providers.¹² Subsequently, Dutch citizens are required to purchase a basic insurance package from a health insurer of their choice. Concerning fertility care, this basic package covers treatment and medication costs for OI, IUI, and three cycles of IVF / ICSI per episode.

The burden of infertility and its treatment

Infertility could be considered a multidimensional stressor for infertile couples, as it affects them in a number of ways.^{13,14} First, patients' threat of staying childless evokes feelings of depression and helplessness and could therefore be considered an important stressor.^{13,15,16} Second, the physical burden of the treatment can cause feelings of anxiety among especially infertile women.^{13,17} Third, infertility often influences the couples' social network or even their own relationship, as most patients find it difficult to talk about their problem to their partner, family and friends.^{14,18} Finally, patients' emotional response to the fertility treatment has a cumulative effect on their emotional status, because patients' levels of quality of life (QoL) decreases with a growing number of unsuccessful cycles.¹⁹ This is underlined by the fact that about 17 to 70 percent of couples end their treatment prematurely, mainly because of the physical and emotional burden they experience.^{9,17,20-23}

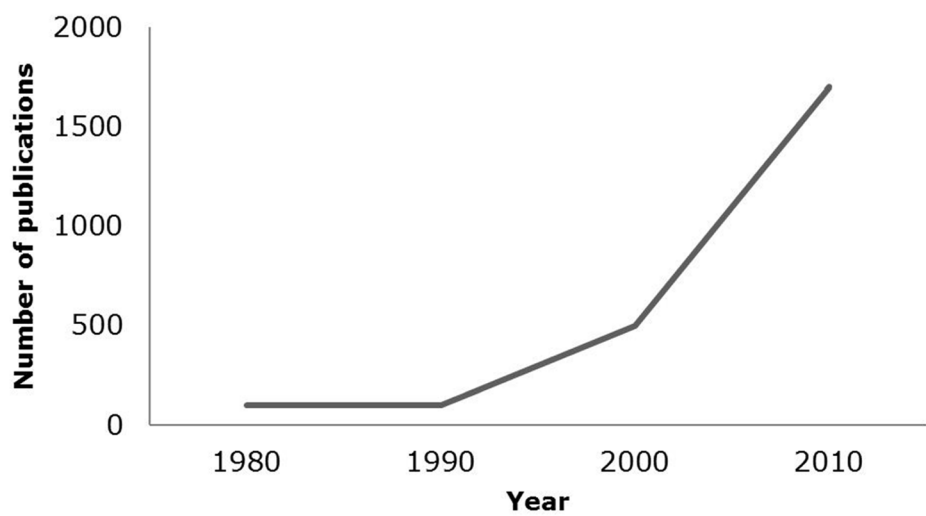
Obviously, infertility is associated with many psychosocial factors and a significant proportion of the infertile population suffers from these stressors. To help professionals within the field of fertility care to detect patients at risk of emotional maladjustment and to identify who could benefit from additional psychosocial support, two instruments have been developed in recent years.^{24,25} The first instrument is the FertiQoL questionnaire, a disease-specific instrument measuring infertile patients' QoL. This questionnaire is also useful in gathering specific information about the 'Mind-Body', 'Emotional', 'Relational' and 'Social' status of the patient.²⁵ The second instrument is the SCREENIVF questionnaire, a screening instrument to determine which patients are at risk of emotional maladjustment during treatment. The questionnaire includes parts of both generic and disease-specific instruments and provides information about patients' level of anxiety, depression, helplessness, lack of acceptance regarding their fertility problem, and lack of social support.²⁴

The FertiQoL and SCREENIVF questionnaires are used in this thesis to determine infertile patients' level of QoL and their emotional status, respectively. However, they are not the only relevant outcome measures for patients suffering from infertility.

What do patients want?

Not every couple visiting a clinic for their fertility problem has the same needs. Obviously, a couple’s primary goal is to achieve pregnancy, but the additional needs and expectations might differ across couples. For example, one couple only wants to become pregnant, irrespective of the remaining quality of care. However, another couple wants to become pregnant, but also wants to receive the most recent and comprehensive information. Meanwhile, the third couple wants to be optimally involved in all decisions regarding their treatment, next to their wish of becoming pregnant. This underlines the uniqueness of each patient as a person. Therefore, professionals in fertility care should keep this in mind by providing not only effective, but also patient-centred care. Patient-centredness is defined by the Institute of Medicine as care that is ‘respectful of and responsive to patients’ preferences and needs and that is guided by patients’ values’.²⁶ Alongside safety, effectiveness, timeliness, efficiency and accessibility, patient-centredness is one of the six dimensions of quality of care.²⁶ Patient-centredness is gaining more and more attention in recent years, as shown in figure 1. Especially in the last decade, the number of publications about patient-centredness of care increased significantly.

Figure 1.
Number of publications per year regarding patient-centred care



Source: Pubmed, searched for: patient-centred or patient-centered

Recent studies from primary and secondary care have shown that providing patient-centred care has several advantages, as it relates to improved health outcomes²⁷⁻²⁹, increased professionals' job satisfaction³⁰⁻³² and reduced healthcare costs.^{28,29,33} Moreover, studies indicate that patient-centred care increases patients' level of QoL.³⁴

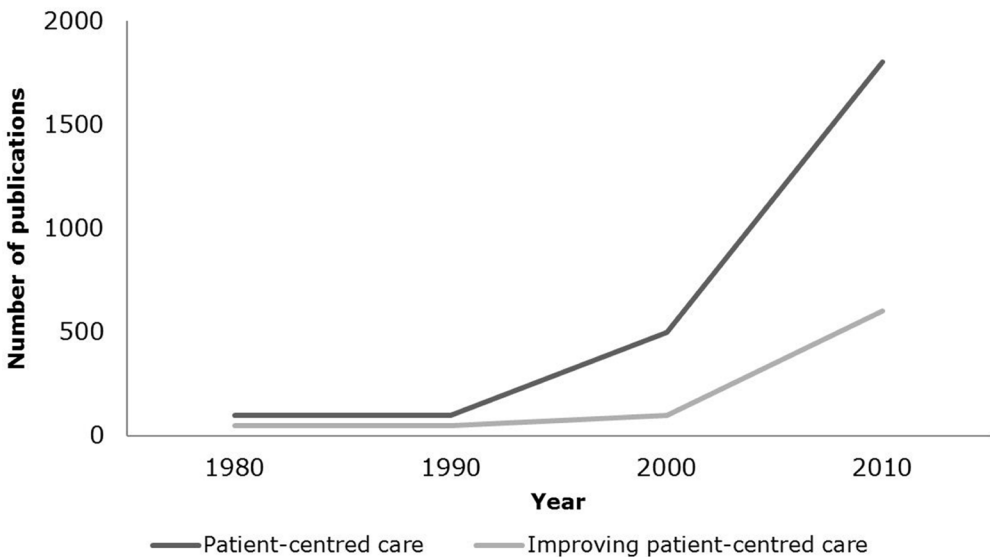
Obviously, all fields of medicine could benefit from patient-centred care, but it might be more relevant to healthcare areas which are associated with high emotions and intensive treatment periods, like fertility care.^{27,35,36} Therefore, every fertility clinic should optimize its care towards patient-centredness by taking into account their patients' preferences and needs. More concrete, as patient-centredness is a multidimensional concept including different elements³⁷, professionals should pay attention to these specific elements in daily practice. In an international context however, the content of these elements is not explicit and varies among the different models of patient-centredness that have been developed in recent years.^{26-29,38-41}

In this thesis, we will determine the level of patient-centred fertility care using the recently developed and validated Patient-Centredness Questionnaire – Infertility (PCQ-Infertility). The content of this instrument was based on both quantitative and qualitative research and includes elements of the patient-centredness models of both the Institute of Medicine and the WHO responsiveness model.^{38,40} The PCQ-Infertility is an objective instrument as it asks about 46 specific patients' experiences with fertility care.⁴² Consequently, the PCQ-Infertility is a more objective instrument than many other satisfaction surveys, as they mainly provide an overly optimistic picture of patients' perception of health care.^{43,44} Next to an overall level of patient-centredness, the PCQ-Infertility covers seven different dimensions or subscales, namely: Accessibility of care, Information provision, Communication, Respect for patients' values, Continuity and transition of care, Patient involvement, and Professionals' competence.⁴²

What we already know about patient-centred fertility care

Many advantages of providing patient-centred care have already been mentioned, but we need some more arguments to stress out the urge of improving this kind of care. For the first argument, we will modify figure 1 by adding a line that represents the number of publications concerning the *improvement* of patient-centred care. As can be seen in Figure 2, studies focusing on improving this kind of care are definitely behind and need more attention.

Figure 2.
Differences between the number of publications regarding patient-centred care and the improvement of patient-centred care



Source: Pubmed, searched for: patient-centred or patient-centered and improve*

Another important argument could be found in the fact that patient-centred care is considerably important to infertile patients themselves⁴⁵⁻⁴⁷, even if we compare it to pregnancy rates.⁴⁸ Patients were willing to trade-off up to a third of their pregnancy rate for more patient-centred care. Moreover, a lack of patient-centredness was one of the main reasons for patients to change fertility clinics.⁴⁸ In addition, also physicians found patient-centred care important, but would trade-off less pregnancy rates for patient-centredness compared to their patients.⁴⁸

Obviously, both patients and professionals in Dutch fertility care attach significant value to patient-centredness. However, van Empel *et al.* showed that the actual level of patient-centred fertility care is variable.⁴² In general, Dutch fertility care was already on the right track concerning the dimensions 'Communication', 'Patient involvement' and 'Competence'. Considerable improvement, though, seemed to be necessary at the dimensions 'Information provision', 'Respect for patients' values' and 'Continuity and transition of care'.⁴² But maybe even more important, the 29 participating Dutch fertility clinics significantly differed on their individual levels of patient-centred care, making it possible to distinguish between 'weak' and 'strong' performing fertility clinics.⁴² Therefore, the results from the PCQ-Infertility could be useful for benchmark purposes, possibly stimulating the 'weak' clinics to improve their level of patient-centredness.⁴⁹⁻⁵¹

Following this, we should be aware which patients and clinic characteristics are associated with patient-centred care. In different healthcare areas, many characteristics have been related to positive experiences with care, such as age, gender, race, marital status, health status, hospital size, continuity of care and length of stay.⁵²⁻⁵⁵ Also in the area of fertility care, some associations have been found. For instance, higher female age, a lower level of education, being pregnant, undergoing IVF/ICSI treatment, having a serious medical history, having a lead physician, and seeing trained fertility nurses were significantly related to more patient-centred care.^{56,57} These characteristics should be taken into account when evaluating a fertility clinic's level of patient-centredness.^{56,58}

Previous studies regarding patient-centred fertility care have not only focused on the opinion of patients, but included fertility care professionals as well. A study in Dutch fertility care showed that professionals could not adequately evaluate their performance regarding the care experiences of their patients, as they significantly misjudged 29 of the 46 PCQ-Infertility items.⁵⁹ As a result, they overestimated one out of seven patient-centredness dimensions and underestimated even four dimensions.⁵⁹ This corresponds to findings from other healthcare areas, where physicians' perceptions about the general quality of care and the perception of their patients were poorly correlated.⁶⁰⁻⁶³ Apparently, professionals have little understanding about the level of patient-centred care they provide and might need help and information to make them more aware.

Gaps in our knowledge regarding patient-centredness

The previous paragraph illustrated that we are moving in the direction of patient-centred fertility care. However, if we want to continue this process and focus on improvement, we should optimize our knowledge regarding this subject first. Based on the current literature, we can state that some important knowledge is lacking.

First, patient-centredness should be put in a broader perspective and related to other patient reported outcome measures, such as QoL, anxiety, and depression. Within other healthcare areas, it is already shown that patient-centredness corresponds to a higher level of patients' QoL or patients' well being.^{33,64-67} Remarkably, this relation has never been studied in the area of fertility care, despite the existing knowledge about the emotional burden of infertility.^{13,14} A strong association between patients' well-being and patient-centred care might indicate that we should take patients' well being into account when measuring patient-centred fertility care and could underline the importance of improving patient-centred care. Moreover, it would be valuable to determine the role of patient-centred care in patients' decision to drop out treatment. A significant proportion of couples do not achieve pregnancy, because they decide to discontinue their treatment prematurely.^{9,17,20-23} In case of a strong association between patient-centred care and dropout, professionals could be motivated even more to focus on the improvement of patient-centred care as it will positively influence their dropout rates.

Further, we noticed that partners of infertile couples are only rarely involved in research⁶⁹⁻⁷¹, while infertility is the perfect example of a condition involving both the woman and her partner. Especially, if we want to aim at the improvement of patient-centred fertility care, we should be aware of the emotional status, the ideas and preferences of both members of the infertile couple.

Finally, we already showed some study results about the preferences of patients and professionals regarding patient-centredness.⁴⁸ Because these results were highly interesting, we should go one step further now and determine the relative value of patient-centred fertility care by calculating its monetary value. This is especially valuable in the current economic situation where costs are becoming more and more important. Moreover, because of the unique Dutch healthcare system, which is based on managed competition between health insurers and providers, we should be aware of insurers' preferences regarding fertility care. The value patients and health insurers place on patient-centred fertility care might be stimulating for policy makers, clinicians and clinics to improve these aspects of care and increase the overall value patients derive from their treatment.

Towards improving patient-centred fertility care

"Es ist nicht genug, zu wissen, man muß auch anwenden;

es ist nicht genug, zu wollen, man muß auch tun."

(Knowing is not enough, we must apply; willing is not enough, we must do.)

Johann Wolfgang von Goethe

This citation illustrates that we have to do more than just gaining knowledge about patient-centred fertility care. If we want to come to improvement, additional steps are needed. Within the area of fertility care, only a few studies focused on the improvement of fertility care aspects that were related to patient-centredness.^{74,75} As the number of these studies is scarce and the results are variable, we should consider the results from studies in other healthcare areas to find out how an optimal improvement strategy should look like.

In the literature, a growing number of interventions to promote patient-centred care are present, but the understanding of the effects of these interventions is still relatively poor.³⁴ Interventions that are mentioned most often are: audit and feedback, reminders, educational outreach visits, patient-directed interventions, and patient-centred training for professionals.³⁴ However, the effects of these single interventions were only small to moderate in most studies.⁷⁶⁻⁷⁸ Because the implementation of a change in professionals' performance or clinics' organization is a complex process, many studies combine two or more single interventions^{34,76}, resulting in a potentially more effective multifaceted approach.^{43,79,80} Unfortunately, only a few studies evaluated the effect of a multifaceted intervention on patient-centred care against a control group (i.e. no intervention)⁷⁶, making it difficult to analyze and interpret the effect of multifaceted interventions. Moreover, most studies vary considerably in their methodological quality and intensity.^{34,76}

In this light, it seems not only important to come to an optimal improvement strategy, but to create optimal circumstances for improvement as well. Studies have shown that for example the culture of a clinic, the organizational 'readiness for change' and organizational commitment could influence a clinic's performance.⁸¹⁻⁸⁴ Whether there are any effective and generalisable strategies to change these characteristics of a clinic is still debatable, and more evidence is therefore needed.⁸⁵

In conclusion, paying attention to patient-centredness of care is gaining more and more attention in daily practice nowadays. Especially patients suffering from infertility could benefit from patient-centred care, as fertility treatments are a

physical and psychological burden to them. Previous studies have shown that the level of patient-centred fertility care varies considerably among clinics and improvement is needed. However, no golden standard is available on how to promote and improve patient-centred fertility care.

Aim and outline of the thesis

The aim of this thesis was to improve patient-centredness in fertility care. However, to come to an optimal improvement design, we needed to put the concept of 'patient-centred fertility care' in a broader perspective first. This thesis is therefore divided into two parts.

In the first part, we created a proper basis to come to an optimal intervention for improving patient-centred fertility care. Therefore, we explored the relation between patient-centredness and other patient related outcomes, such as QoL. Moreover, we studied whether patients' experiences with fertility care and their emotional status differed between women and their partners. Also the relation between patient-centred fertility care and patients' decision to discontinue treatment prematurely (i.e. dropout) was subject of this thesis. Finally, we determined the monetary value of patient-centredness, by studying what both patients and health insurers were willing to pay for more patient-centred fertility care.

In the second part, we studied the effect of audit and feedback on the level of patient-centredness in Dutch fertility care. Subsequently, using the input of both patients and professionals, we composed a multifaceted approach aiming at the improvement of patient-centred fertility care and studied the effectiveness of this intervention. Moreover, we examined the costs, explored determinants at the patient and clinic level of an improvement in patient-centred care and performed an in-depth process evaluation of the multifaceted strategy.

The main questions of this thesis are:

Part I. Patient-centred fertility care in a broader perspective

1. How do patient-centred care, quality of life and distress relate to each other in fertility care? (*Chapter 2*)
2. Do infertile women and their partners differ regarding their fertility care experiences, quality of life and risk factors for emotional problems? (*Chapter 3 and 4*)
3. Can we use the level of patient-centredness as a predictor for dropout in fertility care? (*Chapter 5*)
4. What is the monetary value of patient-centred fertility care? (*Chapter 6*)

Part II. Improving patient-centred fertility care

5. What is the effect of audit and feedback on the improvement of patient-centred fertility care? (*Chapter 7*)
6. Which aspects should be included into an optimal improvement design for patient-centred fertility care according to professionals? (*Chapter 7 and 8*)
7. What is the (cost-)effectiveness of a multifaceted approach on the improvement of patient-centred fertility care? (*Chapter 9 and 10*)
8. Which determinants at the patient and clinic level are associated with an increase in the level of patient-centredness? (*Chapter 9 and 10*)

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"WE WILL GET YOU PREGNANT, LADY!" THESE WERE LITERALLY THE WORDS OF THE DOCTORS WHO WOULD MAKE SURE THAT I GOT WHAT I WANTED: A BABY. OF COURSE, I KNEW THAT THE CHANCE TO ACHIEVE PREGNANCY WAS FAR FROM GUARANTEED, BUT IT SOUNDED LIKE: "PLEASE, DO NOT THINK TOO MUCH ABOUT IT. YOUR GYNAECOLOGY WILL MAKE SURE THAT IT WILL ALL TURN OUT WELL." BUT NO, THIS WAS DEFINITELY NOT WHAT I EXPECTED FROM A PATIENT-CENTRED CARE? I CAN ANSWER THIS QUESTION WITH A CATEGORICAL NO. MY HUSBAND AND I EXPERIENCED DURING THE FIVE YEARS THAT WE WERE WAITING FOR A CHILD DURING THESE YEARS, WE WENT THROUGH DIFFERENT POSITIVE AND NEGATIVE EXPERIENCES. AFTER I HAD UNDERGONE A LAPAROSCOPY TO FIGURE OUT WHY I WASN'T GETTING PREGNANT, A NEW APPOINTMENT WITHIN TWO WEEKS TO START UP A NEW TREATMENT WAS SURPRISINGLY ANSWERED: 'THIS MUST BE A MISTAKE, BECAUSE IT'S TOO EARLY AFTER SURGERY. OBVIOUSLY, YOUR BODY NEEDS MORE TIME TO RECOVER.' BUT THAT WAS REALLY WHAT THE DOCTOR HAD TOLD ME. BUT BEFORE I COULD GO HOME, MY COLLEAGUE. AGAIN, SHE ONLY CONFIRMED WHAT HER COLLEAGUE HAD SAID. MY RETURN WITHIN TWO WEEKS TO CONTINUE MY TREATMENT (AND I HAD TO WAIT FOR THE SECRETARIES, WHO WERE ALSO FIRM IN THEIR STATEMENTS. I COULD GO HOME, BUT THERE WAS NO PROBLEM TO SEE THE DOCTOR AND THERE WAS NOTHING TO WORRY ABOUT. I WAS VERY INSECURE AND HAD STRESSED ME OUT, WHICH OBVIOUSLY HAD TO SIT NEXT TO PATIENTS WHO WERE ALREADY PREGNANT AND WATCHING THE PROGRESS OF THEIR PREGNANCIES TOGETHER. THAT'S GOOD FOR INFERTILITY. IT WAS VERY HARD FOR ME TO SEE ALL THESE BIG BELLYS. MY DOCTOR ASKED ME TO RETURN TO THE WAITING ROOM FOR A FEW MORE MINUTES. THERE I WAS, SITTING NEXT TO A MOTHER WITH A TWO-YEAR OLD CHILD. I WANTED TO PUT MYSELF IN HER SHOES AND FELT REALLY MISERABLE. MY DOCTOR WAS NOT REALLY IMPRESSIVE. FOR EXAMPLE, IT HAPPENED SEVERAL TIMES THAT MY APPOINTMENT. OBVIOUSLY, THE DOCTOR WAS NOT AWARE OF THE FACT THAT I HAD READ MY MEDICAL RECORD BEFORE I ENTERED THE ROOM. ALSO, THE INFORMATION WAS CONTRADICTORY. IT SEEMED LIKE ALL DOCTORS HANDLED OUR CASE DIFFERENTLY. IT SCARED ME A LITTLE BIT, AS I ALREADY FELT PSYCHOLOGICAL PRESSURE. THAT MY DOCTORS WERE ALL POINTING IN THE SAME DIRECTION. I FELT THAT OUR OWN DOCTOR SHOULD NEVER HAVE INTRODUCED THE IVF TREATMENT OPTIONS. VERY CONFUSING, AS WE DID NOT KNOW WHAT THE NEW TREATMENT I READ ABOUT IN A MAGAZINE. OUR DOCTOR HAD SAID THE OPPOSITE WAS TRUE ACCORDING TO THE ELIGIBILITY CRITERIA FOR THIS TREATMENT BEFORE. EVENTUALLY, I WAS THOUGHT TO BE ELIGIBLE FOR THIS TREATMENT. MY HUSBAND AND I WENT FOR AN ULTRASOUND CHECK-UP, A LOT OF SMALL FOLLICLES WERE VISIBLE. MY DOCTOR POINTED TO ME, BUT MY DOCTOR JUST SAID: 'LOOKS FINE. BUT THIS IS NOT WHAT YOU NEED OF COURSE!' WELL, MY DOCTOR SAID: 'I WOULD LIKE TO SHARE, IS ABOUT MY ADMISSIBLE LOSS DURING MY PREGNANCY. YES, WE FINALLY GOT PREGNANT AFTER SEVERAL YEARS. THEREFORE, IT WAS EVEN MORE STRIKING THAT MY DOCTOR ENTERED MY ROOM: 'IT IS VERY NICE AND QUIET ON THIS SECTION!' MY DOCTOR ASKED ME HOW I WAS DOING. I TOLD HIM: 'I'M NOT ALLOWED' TO GO HOME, HE SAID. HE OBVIOUSLY THOUGHT THAT I HAD A PERFECT EXAMPLE OF 'TALKING ABOUT THE PATIENT', INSTEAD OF

CHAPTER 2

HOW PATIENT-CENTRED CARE RELATES TO PATIENTS'

QUALITY OF LIFE AND DISTRESS:

A STUDY IN 427 WOMEN EXPERIENCING INFERTILITY

Abstract

Background

The aim of this study was to investigate to what extent patients' experiences with fertility care are associated with their quality of life (QoL), and levels of anxiety and depression.

Methods

We performed a cross-sectional questionnaire study within 29 Dutch fertility clinics, including women with fertility problems. Through multilevel regression analyses, associations between patients' QoL (FertiQoL) and distress [anxiety and depression; Hospital Anxiety and Depression Scale (HADS)] and their experiences with fertility care [Patient-centredness Questionnaire (PCQ)-Infertility] were determined. For all multilevel models, R^2 and intra-cluster correlation coefficients were calculated.

Results

This study included 427 non-pregnant patients who filled out the FertiQoL, HADS and PCQ-Infertility (response rate 76%). Multilevel regression analysis showed significant associations between the PCQ total scale, the total FertiQoL scale ($B = 0.25$), and HADS subscales ($B = 20.22$ and 20.18). Of the variance in patients' experiences, 13% ($=R^2$) could be explained by their perceived QoL, 12% by their level of anxiety and 10% by their level of depression.

Conclusions

Patient-centredness in fertility care and the patients' QoL and anxiety and depression scores are related. Paying attention to these variables could lead to positive care experiences and improved patient-centredness of care. Future research should focus on identifying causal relationships among these variables.

Introduction

Traditionally, quality of fertility care focuses on outcome measures, such as effectiveness and safety.^{1,2} However, in the last decade, patient-centredness has increasingly been recognized as an important component of high-quality fertility care.³⁻⁵ Patient-centred care is one of the six quality-of-care dimensions and is defined as 'providing care respectful of and responsive to individual patient preferences, needs and values, and ensuring that patient values guide all clinical decisions'.³ The patient-centredness questionnaire-infertility (PCQ-Infertility) was developed and validated as a reliable instrument to measure patient-centredness of fertility care by asking patients about their experiences with care.⁵ By measuring the level of patient-centredness, clinics will have detailed insight into their performance according to patients, and this will allow tailored quality improvement and benchmarking.⁵

The delivery of patient-centred care could bring patients many benefits, especially when it comes to their perceived well-being. Tailoring care in a patient-centred way could remove some of the emotional burden of infertility, often seen in terms of poorer quality of life (QoL) and higher anxiety and depression.⁵⁻⁸ This potentially beneficial relationship between patient-centredness and a patient's well-being has often been discussed, but has not yet been investigated in reproductive medicine.^{4,5}

A methodological problem of using patient self-report measures such as the PCQ-Infertility as indicators for quality of fertility care is that patients' experiences may be influenced by their well-being. It is known that performance on different types of cognitive tasks, including completing questionnaires, can be influenced by the patient's mood.⁹ A positive mood can enhance recall of happy memories^{10,11}, whereas negative affect can result in negative memory biases in patients' self-report measures.¹² This influence might especially apply to infertile patients because infertility is associated with a high emotional burden.^{6,13} Because of this emotional impact^{6,14}, it would not be surprising if a patient's well-being impacted on their reports about experiences with care. It is thus important to know to what extent patient negative or positive mood influences their evaluation of the patient-centred performance of their fertility clinic. A strong association between these would indicate the need to take well-being into account when we measure patient-centredness using the PCQ-Infertility.

To gain more insight into these associations, the objective of this cross-sectional study was to determine how patients' reported experiences with fertility care are related to their well-being (i.e. QoL, anxiety and depression).

Materials and Methods

Setting and study design

This cross-sectional study was nested in another study which aimed primarily at collecting couples' care experiences and validating the PCQ-Infertility.⁵ In order to address secondary research questions^{7, present study} during this large multicentre study, data were also collected on QoL and levels of distress from a subset of the female partners of the participating couples. A total of 29 Dutch fertility clinics from three regions in the Netherlands approved participation in data collection.

Recruitment of patients and inclusion and exclusion criteria

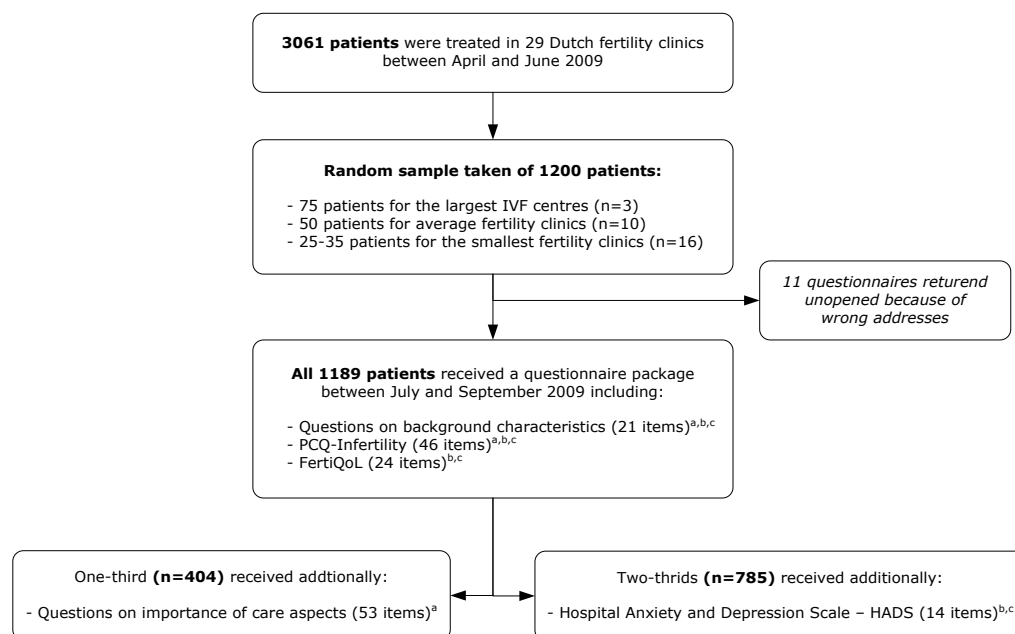
In the Netherlands, every patient visiting a Dutch hospital is assigned a code for insurance purposes according to the patient's diagnosis and treatment. Using this diagnosis treatment combination (DBC) coding system, participating fertility clinics were able to extract from their system the addresses of all patients who underwent medically assisted reproduction in their clinic between April and June 2009, varying from IVF and ICSI to ovulation induction and intrauterine insemination. From these lists of patients ($n = 3061$ individual women), we selected a random sample of 1200 to participate in the total study, and 1189 actually received the questionnaires. The number of sampled patients per clinic depended on the size of their infertility outpatient clinic, ranging from 25 patients for smaller clinics to 75 for the largest IVF centres. For the study described in this paper, we randomly selected two-thirds of patients per clinic because of practical reasons ($n = 785$). Per fertility clinic, we alternately allocated patients to participation in the study. The time interval between the last treatment date and the date of filling out the questionnaire could vary between one month (June–July 2009) and five months (April–September 2009). The full selection procedure is depicted in figure 1. When completing the questionnaires, most women were expecting or undergoing another fertility treatment; others were awaiting the outcome of the previous fertility treatment or had recently achieved pregnancy. Those who had become pregnant during the study were excluded from the analyses, as most questions of FertiQoL are no longer applicable (e.g. 'Do your fertility problems interfere with your day-to-day work or obligations?').

Ethical approval

The institutional ethics committee of Radboud University Medical Centre Nijmegen reviewed and provided ethical approval for this research project to proceed.

Figure 1

Overview of patient selection of the multicentre study in which the present study was nested.



^a Validation study PCQ-Infertility⁵

^b Validation study Dutch FertiQoL⁷

^c Present study

Data collection

We sent patients the survey and they received a reminder card 3 weeks after the initial mailing. After another 2 weeks, non-responders received an additional reminder with a new copy of the questionnaire.

Measurement instruments

In fertility care, we can reliably assess well-being by QoL and distress (i.e. anxiety and depression), using the FertiQoL questionnaire and the Hospital Anxiety and Depression Scale (HADS).⁷ The internationally developed and validated FertiQoL questionnaire consists of 26 questions. Besides two general items, it contains 24 specific items covering four subscales of QoL: Mind–Body (e.g. 'Do your fertility problems interfere with your day-to-day work or obligations?'), Relational (e.g. 'Have fertility problems strengthened your commitment to your partner?'), Social (e.g. 'Are you socially isolated because of fertility problems?') and Emotional

(e.g. 'Do you feel able to cope with your fertility problems?'). The optional FertiQoL treatment module was not used in this study. A higher score on one of the subscales means a better QoL with subscale scores ranging from 0 to 100 (see Boivin et al., 2011, and Aarts et al., 2011, for further information on FertiQoL development and validity). The Dutch FertiQoL has shown good reliability in a previous study: Cronbach's α varied between 0.72 and 0.91.⁷

The HADS was used to measure anxiety and depression in our study population. This questionnaire comprises 14 items: a 7-item anxiety subscale and a 7-item depression subscale. Cronbach's α of these subscales was 0.82 and 0.83, respectively, in the same sample of Dutch patients experiencing infertility.⁷ Subscale scores range from 0 to 21: a higher score means higher levels of anxiety and depression, respectively.^{15,16} A score of 8 is set as a cut-off value suggestive of a psychiatric condition.^{15,16}

Finally, we used the PCQ-Infertility (46 items), a validated instrument measuring the level of patient-centredness in fertility care, to assess patients' experiences with care. This questionnaire is subdivided into seven different domains: accessibility (e.g. 'Was it a problem for you to contact staff if you had any questions?'), information (e.g. 'Did you receive an overview of your treatment plan with a time schedule?'), communication (e.g. 'How often did your physician take you seriously?'), respect for patients' values (e.g. 'How often did your physician show an interest in your personal situation?'), continuity and transition (e.g. 'How often did you have an appointment with the same physician?'), patient involvement (e.g. 'Was decision-making shared with you, if preferred?') and competence (e.g. 'How often was your physician well-prepared for an appointment?'). Cronbach's α was high among across these domains (range 0.64–0.83).⁵ Higher scores on the total PCQ scale or one of these subscales (range 0–3) means a higher level of patient-centredness (see Van Empel *et al.* for details of the PCQ-Infertility)⁵.

Data analyses

We entered data into an SPSS database (version 16.0 for Windows, SPSS Inc., Chicago, IL, USA). As mentioned above, we excluded pregnant women from the analyses. We performed a multilevel regression analysis to adjust for clustering of patients within the same clinics. Additionally, the validation study of the PCQ-Infertility had shown that the level of patient-centredness differed significantly between clinics (Van Empel et al., 2010a). We standardized variables to the unit of measurement which differed between the three instruments (i.e. 0–3, 0–21, and 0–100, respectively). We therefore converted the scores of the PCQ variables and the HADS variables to the same unit of measurement as the FertiQoL scores (0–100) by multiplying these by 33.33 and 4.76, respectively. In the analyses,

we applied these standardized scores, but for the descriptive statistics, we used original units of measurement. We chose to use the level of patient-centredness as the dependent variable and patient's QoL and level of anxiety and depression as the independent variables, because this way we emphasized patient-centredness as an important outcome measure of quality of fertility care.

We thus considered the total scale of the PCQ-Infertility the dependent outcome variable. Per patient, a mean PCQ total score was calculated by summing up the responses to the individual items and dividing these scores by the number of items completed.⁵ Patients who filled out half or less of the items within a subscale were to be excluded from further analyses. However, this was never the case in this study.

We used the patient's QoL, and levels of anxiety and depression as potential correlates for the level of patient-centredness. Consequently, we considered the total scale and all subscales of the FertiQoL, and HADS-anxiety and HADS-depression scales as independent variables. For the total scale and subscales of the FertiQoL, we calculated a mean score per patient (range 0–100).⁸ HADS subscale scores were calculated by summing up the responses to the individual items. Additionally, as the patient characteristics 'type of treatment' and 'women's level of education' were found to be associated with the level of patient-centredness in the validation study of the PCQ-Infertility⁵, we used these variables as additional case-mix adjusters.

We computed multilevel regression models to determine the effects of the independent variables on the level of patient-centredness. The first model contained no covariates (model 0) and was the reference to which we compared seven other models with adjustment for three independent variables, which were: type of treatment, women's education and one of QoL, anxiety or depression. Models 1, 2 and 3 contained the total FertiQoL, HADS-anxiety and HADS-depression scores, respectively. Models 4–7 adjusted for the FertiQoL subscales 'Emotional', 'Mind–Body', 'Relational' and 'Social', respectively. In the eighth model, we entered HADS scales and the total FertiQoL all together to determine what independent variable, taking into account the others, would be the most important predictor in this model for patient-centredness of care. In this last model, we did not exclude non significant variables, because we aimed with this particular analysis to elicit what independent variable had the strongest association with the dependent variable, when including the others.

Furthermore, we calculated intra-cluster correlation coefficients (ICCs) to evaluate which part of the variance in patient-centredness is related to differences between fertility clinics. We determined this level of relatedness of clustered data

by comparing the variance within clusters with the variance between clusters (range 0–1). In this study’s analyses, a cluster was set at the level of fertility clinics. We calculated the ICCs using the 0-model as described before.

Finally, we determined explained variance by calculating R^2 , indicating what percentage of variance in patient-centredness is attributable to the level of patient’s QoL, anxiety and depression. Significance for all analyses was set at $P < 0.05$.

Results

Respondents

In total, 594 patients filled out the PCQ-Infertility, the FertiQoL questionnaire and the HADS (response rate 76%). Of these, 167 women (19%) were pregnant and were therefore excluded from further analyses. The median age of the remaining participants ($n = 427$) was 33 years (range 20–45). Of these women, 8% had a non-Dutch ethnicity and 42% of them had a high educational level (i.e. higher professional education or university according Dutch standardized definitions). Their median duration of infertility was 34 months and 72% of women were childless. Infertility was due to a male or female factor in 26 and 27% of cases, respectively. In 10%, both male and female factors were reported, and 37% of patients suffered from unexplained infertility. Half of participants underwent IVF and/or ICSI treatment. Table 1 presents their mean scores on the total scale and subscales of all three measurement instruments.

Table 1
Total scores and subscale scores of all three measurement instruments (n=427)

PCQ-Infertility (range 0-3)	Mean (SD)	FertiQoL (range 1-100)	Mean (SD)	HADS (range 0-21)	Mean (SD)
Total	2.2 (0.4)	Total	70.8 (13.9)	Anxiety	5.6 (3.9)
Accessibility	2.1 (0.8)	Emotional	59.8 (18.7)	Depression	3.5 (3.3)
Information	2.0 (0.6)	Mind-body	70.8 (19.5)		
Communication	2.5 (0.5)	Relational	78.2 (14.5)		
Respect for patients’ value	2.1 (0.8)	Social	74.0 (16.6)		
Patient involvement	2.4 (0.6)				
Continuity and transition	2.0 (0.6)				
Competence	2.5 (0.4)				

PCQ-Infertility = Patient Centredness Questionnaire-Infertility; SD = Standard Deviation
HADS = Hospital Anxiety and Depression Scale

Multilevel regression model

Table 2 describes the results of the multilevel regression analyses. When adjusted for 'type of treatment' and 'women's level of education', Models 1, 2 and 3 showed that lower levels of anxiety, lower levels of depression and a higher QoL are significantly associated with perceptions of more patient-centred care ($B = 20.22$, 20.18 and 0.25 , respectively). In Models 4–7, the analysis showed significant associations between the PCQ total scale and every FertiQoL subscale ($B = 0.148$ – 0.239), when adjusted for the aforementioned patient characteristics, indicating that better QoL in the Social, Emotional, Relational and Mind–Body domains is associated with a higher level of patient-centredness of care. The eighth model showed that higher scores on the FertiQoL total scale was significantly associated with higher levels of patient-centredness, when anxiety and depression were taking into account, suggesting that this is the most important variable of those three, when predicting patient-centredness of care. In four additional models, containing both HADS scales and each of the four FertiQoL subscales separately, it showed that the Social subscale added the most, when corrected for anxiety and depression ($B = 0.137$; $P = 0.001$). Table 2 also lists the ICC's, indicating that the variance in patient-centredness of participating clinics appeared to be 12–15%.

Finally, the 8–13% of the variance in patient-centredness described in this study was attributable to the patient's level of QoL, anxiety and depression (R^2 , last row).

Discussion

Patient-centredness of fertility care and patients' well-being are related. Patients with a better QoL or lower levels of anxiety and depression report higher levels of patient-centred fertility care. However, as this is a cross-sectional study, associations could also be presented the other way around: more patient-centred care is related to a higher QoL and lower levels of anxiety and depression. We discuss both directions in more detail below.

First, we look into the association between patient-centredness and patients' QoL. To the best of our knowledge, this has never been studied before in a fertility care setting. QoL involves a reflection of patients' functioning in relation to their health status in a broad sense⁷ and links merely to a holistic view on care. Between 8 and 13% of the variance in patients' experiences could be explained by their perceived QoL, indicating that these two concepts are related but distinct as also shown by the relatively weak correlation between the total PCQ–Infertility and total FertiQoL ($B = 0.250$).

Table 2
Multilevel regression analyses: associations between patient centredness and QoL, anxiety and depression

	Model 0 (nul)	Model 1 (FertiQoL Total)	Model 2 (HADS Anxiety)	Model 3 (HADS Depression)	Model 4 (FertiQoL Emotional)	Model 5 (FertiQoL Mind-Body)	Model 6 (FertiQoL Relational)	Model 7 (FertiQoL Social)
Intercept	-0.16 (-0.36-0.03)	-0.25* (-0.45- -0.05)	-0.25* (-0.45- -0.04)	-0.24* (-0.44- -0.03)	-0.25* (-0.45- -0.05)	-0.24* (-0.44- -0.04)	-0.25* (-0.45- -0.04)	-0.25* (-0.45- -0.06)
FertiQoL total		0.25* (0.16-0.34)						
HADS Anxiety			-0.22* (-0.30- -0.13)					
HADS Depression				-0.18* (-0.27- -0.10)				
FertiQoL subscales:								
Emotional					0.18* (0.09-0.27)			
Mind-Body					0.22* (0.13-0.30)			
Relational							0.15* (0.06-0.23)	
Social								0.24* (0.15-0.33)
Women's level of education		-0.23* (-0.40- -0.06)	-0.22* (-0.39- -0.05)	-0.24* (-0.42- -0.06)	-0.22* (-0.40- -0.05)	-0.23* (-0.41- -0.06)	-0.22* (-0.39- -0.04)	-0.22* (-0.39- -0.04)
Type of treatment		0.43* (0.23-0.64)	0.41* (0.21-0.62)	0.42* (0.21-0.63)	0.42* (0.21-0.63)	0.41* (0.21-0.62)	0.41* (0.19-0.62)	0.43* (0.22-0.64)
ICC	0.17	0.12	0.15	0.14	0.13	0.13	0.14	0.12
R ²	0.00	0.13	0.12	0.10	0.09	0.11	0.08	0.13

Coefficients (B) with 95% confidence intervals are demonstrated here. This coefficient describes the difference in PCQ when FertiQoL or HADS levels increase with 1. It also indicates the directions of the mentioned association. For example, the PCQ-Infertility is positively related to the FertiQoL total (B = 0.25), but the HADS anxiety is negatively related to the PCQ-Infertility (B = 20.22).

ICC, intra-cluster correlation coefficient; variance at hospital level/total variance. The amount of variance in patient-centredness attributed to differences between hospitals.

R², explained variance; this represents the percentage of variance in the clinics level of patient-centredness attributable to patient's QoL, anxiety and depression.

*p < 0.05

However, our results might point at the importance of integrating QoL aspects into care delivery and paying attention to anxiety and depression symptoms to improve patient-centredness and quality of care. For instance, when adjusted for patient characteristics, the Social subscale of the FertiQoL appeared to be related the most to patient-centredness of care. This might imply that patients without social support from family rely more heavily on the support provided at the fertility clinic. There are some studies supporting this hypothesis: less family problems were encountered and less psychosocial support was needed when patients' satisfaction with care was high.^{17,18} These findings stress the importance of a comprehensive approach when providing care to patients experiencing infertility. This can also be underlined by our findings that only 12–15% of the variance in patient-centredness was attributable to differences between the participating fertility clinics. Apparently, more than 80% of the variance in patient-centredness is attributable to other elements, which emphasizes the comprehensiveness of this concept.

Another more practical implication to these results involves the question of whether we should adjust fertility clinic's patient-centredness levels for QoL and distress when reporting. In literature, it is not always recommended to do so, as adjustment has a small effect on hospital comparisons mostly.^{19–21} However, if comparisons on the PCQ-Infertility involve groups known to differ on QoL and/or anxiety and depression, then adjustment for these variables will be required.

Second, interpretation of the association the other way around (i.e. more patient centred care is related to a higher QoL and lower levels of anxiety and depression) suggests that a holistic approach to care, including patient-centred care, could potentially reduce short-term effects of treatment on concentration and interference with day-to-day activities (items in Mind–Body domain) or feelings of isolation (items in Social domain). In other health-care areas, researchers showed the beneficial effect of patient-centred care on several clinical, psychological and even economical outcome measures^{22–25}, for instance, improved well-being and reduced costs.^{25,26} Within a fertility care setting, it would be valuable to investigate if more patient-centred care would lead to lower drop-out from treatment rates, which are often substantial.^{27–30} By tailoring care more specifically to the individual patient and taking into account the patient's wishes and needs, we might take away some of the emotional burden of infertility and accompanying treatments.^{5,6,31}

The results of this study are in line with previous studies on the relationship between patients' evaluations of care and their mental health status in fertility care in terms of anxiety and depression.^{21,32} Also in other health-care areas (e.g. medical psychology), researchers described interactions between affect and the

ability of patients to evaluate different situations in care. Affective states play an important role in people's interpersonal behaviours and ability to disclose personal information.^{9,12} On the one hand, this takes place by priming access to only mood-consistent information in memory (e.g. happy mood primes access to happy memories). On the other hand, this occurs by influencing the kind of processing strategies people use: patients suffering from a sad mood are more influenced by external social norms and behaviour of, for example, their partner. This results in a more cautious and reciprocal disclosure of personal information.⁹ For fertility care, this could mean that more anxious and depressive patients might remember more bad experiences with care, underpinning our results, and will also be more cautious in sharing their experiences with care providers.³³ One important difference between previous studies and ours should also be noted: the PCQ-Infertility is a validated measurement instrument assessing experiences with care instead of satisfaction.⁵ Patients' experiences are believed to map the quality of care from a patient's perspective more accurately.^{34,35}

This study has several strengths. First, the large, randomly sampled and diverse study population, together with the high response rate (74%), ensures the representativeness of the Dutch population experiencing infertility. Second, we conducted a multilevel regression analysis. The clustered nature of our data on patients' experiences makes multilevel analysis the preferred method for identifying determinants.²⁰ Some potential weaknesses are also worth considering. First, due to the cross-sectional study design, we cannot draw any conclusions on causality. To evaluate the actual effect that patients' QoL has on the level of patient-centredness would be an interesting subject for future prospective research. Second, the PCQ-Infertility was filled out by the patient couple, whereas the FertiQoL and HADS were completed by the woman only. This discrepancy has to be taken into account when interpreting our results. Several authors reported that men feel marginalized and overlooked in fertility care^{36,37}, although their QoL is mostly higher than that of women.³⁸⁻⁴⁰ The present study was nested in another, because we wanted to reduce the burden for couples of filling out such an amount of questionnaires. However, for future research, it is desirable to include men as well, as knowledge on men's care experiences are also needed to design and develop interventions to improve fertility care services. Third, in this study, we adjusted our results for two patient characteristics, known to be associated with patient-centred fertility care. It would have been valuable if we had also included organizational determinants into the multilevel model, as previous research showed that patients' experiences with care are associated with clinic factors.^{21,41} For instance, providing patients support from a nurse specializing in infertility or granting patients access to their own medical records is a proven practical way of improving patient-centredness of fertility

care services.⁴¹ The interaction between these types of possible determinants and patients' well-being could therefore provide us with valuable information on how to improve our fertility care services. However, these organizational aspects were not available in the present study.

In conclusion, associations exist between the level of patient-centredness in fertility care and patients' QoL and their levels of anxiety and depression. This reflects that paying attention to these patient-related variables and more tailored care could lead to positive well-being and care experiences and improved patient-centredness of care.

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"WE WILL GET YOU PREGNANT, LADY!" THESE WERE LITERALLY THE WORDS OF THE DOCTOR WHO WOULD MAKE SURE THAT I GOT WHAT I WANTED: A BABY. OF COURSE, I KNEW THAT THE CHANCE TO ACHIEVE PREGNANCY WAS FAR FROM GUARANTEED, BUT IT USED TO SOUND LIKE: "PLEASE, DO NOT THINK TOO MUCH ABOUT IT. YOUR GYNÁECOLOGY WILL MAKE SURE THAT IT WILL ALL TURN OUT WELL IN THE END." NO, THIS WAS DEFINITELY NOT WHAT I EXPECTED FROM A PATIENT-CENTRED CARE? I CAN ANSWER THIS QUESTION WITH A CATEGORICAL NO. MY HUSBAND AND I EXPERIENCED DURING THE FIVE YEARS THAT WE WERE WAITING FOR A CHILD DURING THESE YEARS, WE WENT THROUGH DIFFERENT POSITIVE AND NEGATIVE EXPERIENCES. AFTER I HAD UNDERGONE A LAPAROSCOPY TO FIGURE OUT WHY I WASN'T GETTING PREGNANT, A NEW APPOINTMENT WITHIN TWO WEEKS TO START UP A NEW TREATMENT WAS SURPRISINGLY ANSWERED: 'THIS MUST BE A MISTAKE, BECAUSE IT'S TOO EARLY AFTER SURGERY. OBVIOUSLY, YOUR BODY NEEDS MORE TIME TO RECOVER.' THAT WAS REALLY WHAT THE DOCTOR HAD TOLD ME. BUT BEFORE I COULD RETURN TO MY COLLEAGUE. AGAIN, SHE ONLY CONFIRMED WHAT HER COLLEAGUE HAD SAID. MY RETURN WITHIN TWO WEEKS TO CONTINUE MY TREATMENT (AND I HAD TO WAIT FOR THE SECRETARIES, WHO WERE ALSO FIRM IN THEIR STATEMENTS. I COULD NOT GO. THERE WAS NO PROBLEM TO SEE THE DOCTOR AND THERE WAS NOTHING TO WORRY ABOUT. I WAS VERY INSECURE AND HAD STRESSED ME OUT, WHICH OBVIOUSLY OFTEN HAD TO SIT NEXT TO PATIENTS WHO WERE ALREADY PREGNANT AND WERE TALKING ABOUT THE PROGRESS OF THEIR PREGNANCIES TOGETHER. THAT'S GOOD FOR PATIENTS WITH INFERTILITY. IT WAS VERY HARD FOR ME TO SEE ALL THESE BIG BELLYS. THE DOCTOR ASKED ME TO RETURN TO THE WAITING ROOM FOR A FEW MORE MONTHS. THERE I WAS, SITTING NEXT TO A MOTHER WITH A TWO-YEAR OLD CHILD. SHE WANTED TO PUT MYSELF IN HER SHOES AND FELT REALLY MISERABLE. MY OWN EXPERIENCE WAS NOT REALLY IMPRESSIVE. FOR EXAMPLE, IT HAPPENED SEVERAL TIMES THAT I DID NOT GET AN APPOINTMENT. OBVIOUSLY, THE DOCTOR WAS NOT AWARE OF THE FACT THAT I HAD TO READ MY MEDICAL RECORD BEFORE I ENTERED THE ROOM. ALSO, THE INFORMATION WAS CONTRADICTORY. IT SEEMED LIKE ALL DOCTORS HANDLED OUR CASE DIFFERENTLY. IT SCARED ME A LITTLE BIT, AS I ALREADY FELT PSYCHOLOGICAL PRESSURE. THAT MY DOCTORS WERE ALL POINTING IN THE SAME DIRECTION. I FELT THAT OUR OWN DOCTOR SHOULD NEVER HAVE INTRODUCED THE IVF TREATMENT AS ONE OF THE TREATMENT OPTIONS. VERY CONFUSING, AS WE DID NOT KNOW WHAT THE NEW TREATMENT I READ ABOUT IN A MAGAZINE. OUR DOCTOR HAD SAID THAT THE HOSPITAL, WHILE EXACTLY THE OPPOSITE WAS TRUE ACCORDING TO THE CRITERIA ELIGIBLE FOR THIS TREATMENT BEFORE. EVENTUALLY, I WAS TOLD THAT I WASN'T ELIGIBLE BECAUSE OF THE WORSE COMMUNICATION, MY HUSBAND AND I HAD TO GO FOR AN ULTRASOUND CHECK-UP. A LOT OF SMALL FOLLICLES WERE VISIBLE. THE DOCTOR TOLD ME, BUT MY DOCTOR JUST SAID 'YOUR OVARY LOOKS FINE, BUT THIS IS NOT WHAT YOU NEED OF COURSE!' WELL, THAT WASN'T THE ANSWER I NEEDED TO SHARE, IS ABOUT MY ADMIS-

ALEIDA G. HUPPELSCHOTEN

NOORTJE T.L. VAN DUINHOFEN

PETER F.J. VAN BOMMEL

JAN A.M. KREMER

WILLIANNE L.D.M. NELEN

LOSS DURING MY PREGNANCY. YES, WE FINALLY GOT PREGNANT AFTER SEVERAL YEARS. THEREFORE, IT WAS EVEN MORE STRIKING WHEN THE DOCTOR ENTERED MY ROOM: 'IT IS VERY NICE AND QUIET ON THIS SECTION' HE SAID. HE THEN ENTERED MY ROOM AND ASKED ME HOW I WAS DOING. I TOLD HIM THAT I WAS 'ALLOWED' TO GO HOME, HE SAID. HE OBVIOUSLY THOUGHT THAT I HADN'T YET PREFERRED TO STAY ANOTHER DAY. IT WAS A PERFECT EXAMPLE OF 'TALKING ABOUT THE PATIENT', INSTEAD OF

CHAPTER 3

DO INFERTILE WOMEN AND THEIR PARTNERS HAVE EQUAL EXPERIENCES WITH FERTILITY CARE?

Abstract

Objectives

To study the possible differences between women and their partners' experiences with patient-centred fertility care.

Methods

We performed this cross-sectional study within 32 Dutch fertility clinics. A total of 1620 infertile women and their partners, under treatment in one of the participating clinics, were randomly selected to participate in this study. Main outcome measure was the level of patient-centredness, measured with the validated Patient-centredness Questionnaire-Infertility (PCQ-Infertility).

Results

Questionnaires from 696 women and 520 partners could be analyzed. No significant difference in PCQ-Infertility total score was found between women and their partners. The partners scored significantly higher on the subscales 'Respect for patients values' and 'Staff's competence' compared to their women.

Conclusions

Patients' experiences with fertility care are only slightly different between women and their partners. This can be valuable in the process of improvement of patient-centred fertility care, one of the core dimensions of quality of care.

Introduction

Infertility has a great impact on the infertile couple.¹⁻⁴ In general, patients have to undergo a long lasting period of fertility work up and treatment, which can be a physical and psychological burden to them.^{1,5} Therefore, every fertility clinic should focus more on their patients' preferences and needs.⁶ Providing patient-centred care, being one of the core dimensions of quality of care⁶, can improve patients' experiences with fertility care by building caring relationships between patients and professionals^{7,8}, increase patients' quality of life (QoL)^{9,10} and possibly decrease dropout rates.¹¹

Only a few studies explored specific patients' fertility care experiences, by measuring the level of patient-centredness.¹²⁻¹⁶ All studies showed remarkable room for improvement within fertility care.¹²⁻¹⁶ For example, patients expressed a need for more written information about the treatment^{13,15}, and more emotional advice and support.^{12,13,16} Moreover, infertile women expressed the wish for a more couple-centred approach.¹⁵ Providing care to both members of the infertile couple seems obvious, as infertility is the perfect example of a shared condition concerning both partners.¹⁷⁻¹⁹ Therefore, it is remarkable that available fertility care research typically includes infertile couples as a whole²⁰⁻²² or women alone.^{10,15,16,23-25} Partners seems to be a forgotten party.¹⁷⁻¹⁹ Especially if we aim at improving the level of patient-centred fertility care, we should primarily identify possible differences in preferences and needs between women and partners. This is underlined by the results of Malik *et al.*, showing a clear wish of partners also to discuss their feelings and concerns regarding their experiences with fertility care.¹⁹

Gender differences in patients' experiences with care are rarely evaluated in a fertility care setting. Only a few studies have explored gender differences in patients' satisfaction in a fertility care setting.^{12,13,26} Unfortunately, satisfaction surveys often provide an overoptimistic picture of patients' perception of healthcare.^{27,28} Getting insight into more objective patients' experiences with care by measuring the level of patient-centredness would provide more useful and meaningful information. An appropriate and reliable instrument to achieve this goal is the Patient-centredness Questionnaire-Infertility (PCQ-Infertility), which was recently developed and validated.²⁹

Therefore, the main aim of the current study is to compare experiences of women and their partners with patient-centred fertility care using the PCQ-Infertility. Results of this study will provide more insight into the possible different preferences and needs of infertile women and their partners. Moreover, our results can guide the development of an improvement strategy for more patient-centred fertility

care, with accurate adjustment for both members of the infertile couple.

Materials and Methods

Study design

This cross-sectional study was nested within the before measurement of a randomized controlled trial, which aims to improve the level of patient-centredness of Dutch fertility care using a multifaceted approach. For more information on this study, we refer the reader to Huppelschoten, *et al.*³⁰

Setting

In the Netherlands, fertility care is provided by three different types of clinics based on the kind of treatment they offer. Almost all clinics are part of a hospital and carry out initial fertility assessment, ovulation induction (OI) and intra-uterine insemination (IUI). A limited number of clinics can also start and monitor the *In Vitro* Fertilization (IVF) and Intra-cytoplasmic Sperm Injection (ICSI) treatment, including the ovum pickup. The laboratory phase of IVF and embryo transfers has to occur in one of the thirteen licensed clinics; eight university hospitals, four general hospitals, and one private clinic. Almost all Dutch fertility clinics are national health services funded. Every Dutch citizen has a basic insurance coverage, which covers treatment and medication costs for OI, IUI, and three cycles of IVF/ICSI per episode.

Study population

The study was performed in a Dutch infertile patient group, being under treatment in one of 32 Dutch clinics. To include a representative patient group, clinics were asked to extract the address files of all patients who underwent at least one cycle of Medically Assisted Reproduction (MAR) (e.g., OI, IUI, IVF, and ICSI) in their clinics in the past three months (spring-summer 2011) from their diagnosis treatment combination coding system. From this list of patients, we took a computerized random sample of patients which was stratified according to the clinic size, ranging from 25 couples for smaller clinics to 75 couples for the largest IVF centres. As a result, 1620 couples were selected to participate in our study. Both members of the couple were invited to participate in the study individually. Couples of which the woman was pregnant while completing the questionnaire were excluded from analyses, due to a risk of confounding.²⁹

Data collection

Data collection was performed using a questionnaire to measure the level of patient-centred fertility care. Selected women and their partners received a letter in which they were invited to complete an online questionnaire set, accessible by a personal code. Both the women and partners were asked explicitly to complete the questionnaire separately. Participation was voluntary and anonymous. Patients received a reminder card two weeks after the initial mailing. Another three weeks later, non-responders received a reminder with the additional option to complete a paper version of the questionnaire.³¹

Questionnaire

The questionnaire consisted of two parts; the first part was the Patient-centredness Questionnaire – Infertility (PCQ-Infertility), a validated instrument to assess clinic's level of patient-centredness by measuring patients' experiences with fertility care.²⁹ Development of this questionnaire was based on the models of patient-centred care of both the Picker Institute and the Institute of Medicine.^{6,32} The questionnaire consists of 46 items, covering seven subscales: 1) Accessibility of care (e.g. *'Was it a problem for you to contact staff if you had any questions?'*); 2) Information provision (e.g. *'Did you receive an overview of your treatment plan with a time schedule?'*); 3) Communication (e.g. *'How often did your physician listened to you?'*); 4) Respect for patients' values (e.g. *'How often did your physician show an interest in your personal situation?'*); 5) Continuity and transition of care (e.g. *'How often did you have an appointment with the same physician?'*); 6) Patient involvement (e.g. *'Was decision-making shared with you, if preferred?'*); and 7) Staff's competence (e.g. *'How often was your physician well-prepared for an appointment?'*). A higher score on the total PCQ scale or on one of the subscales (range 0-3) implicates a higher level of patient-centredness. Further details on the validation study of the PCQ-Infertility are described in Van Empel *et al.*²⁹

The second part of the questionnaire consisted of eighteen additional individual and couple background questions. These questions were selected as potential case-mix adjusters, based on general and fertility care literature as possibly being associated with patient-centred care.^{21,29,33-35} Background questions included general questions (e.g. age, ethnicity), questions about patients' emotional status (e.g. consumption of emotional support in the last three months, recently experienced life-time events) and questions about past and current treatments (e.g. duration of infertility, diagnosis). Only the women answered the questions about the couple characteristics to prevent incompatible answers from women and their partners. We assumed that the women were most capable of answering

these couple questions as most questions were about the diagnosis and history of fertility treatments.

Ethical approval

The institutional ethics committee of Radboud University Nijmegen Medical Centre provided ethical approval for this research (CMO nr 2011/034).

Data analyses

First, we tested whether responding and non-responding partners in our study differed significantly on the couple characteristics that were gathered in our study (i.e. being a lesbian couple; frequency of visiting the clinic as a couple; median duration of relationship, infertility and experience in fertility care; net monthly family income; diagnosis and treatment type). Chi-square tests and independent t-tests were used for categorical and continuous variables, respectively to compare women with a partner as responder ('complete couples') to women with a partner as non-responder ('incomplete couples').

Data analyses of the levels of patient-centredness within the infertile couple started with a three-step evaluation to determine if case-mix adjustment was necessary. First, a series of univariate regression analyses were performed with the PCQ-Infertility total score as dependent variable. All background characteristics acted as the independent variables. Variables with $P < 0.15$ in the univariate analysis were selected as potential case-mix adjusters. Second, it was tested if the interaction between these background characteristics and gender significantly related to the PCQ-Infertility score. If so, also these interactions were selected as potential case-mix adjusters. Third, correlation analyses with Spearman's ρ were performed to evaluate collinearity between the selected characteristics. In case of two strongly correlating variables ($\rho > 0.60$), the clinically most relevant characteristic was kept.

Subsequently, the main analysis was performed to investigate differences in experiences with patient-centred fertility care within the infertile couple. As both members of the infertile couple will be affected by the unfulfilled child wish, it is more powerful to investigate intra-couple experiences with fertility care instead of comparing a group of infertile women and partners separately.^{17,18} Therefore, analysis was performed with the infertile couple as the unit of analyses. Data were structured so that each line contained data for one individual, with a variable included that defined the couple. Multilevel multivariate regression analyses with manual backward elimination was carried out with the individual (level 1) nested within the couple (level 2). The total scores and corresponding subscale scores of the PCQ-Infertility acted as the dependent variable. Being a women or a partner

acted as the independent variable. Significance for multivariate analyses was set at $P < 0.05$. Analyses were performed using SPSS (version 18.0 for Windows®, SPSS Inc., Chicago, IL, USA).

Results

In total, 946 women (response rate 58%) and 670 partners (response rate 41%) of the 1620 invited couples completed the questionnaires. A total of 250 women and 150 partners (25%) were already pregnant while completing the questionnaire. As a result, 1216 questionnaires were eligible for analyses, 696 from the women and 520 from the partners. Due to the possibility to correct for incomplete couples, it is legitimate that the final sample contained less partners than women.

Table 1 presents the patient and couple characteristics. Non-responder analyses showed significant differences for only one couple characteristic: couples of which both members participated in the study visited the clinic significantly more often as a couple, than couples of which only the women participated in the study (74% vs. 26%, respectively; p -value=0.01).

Table 2 presents the PCQ-Infertility total and subscale scores, stratified by women and partners. The median total score on the PCQ-Infertility was 2.23 (range 0.50-2.98) for women and 2.30 (range 0.56 – 2.98) for partners. Of the initial eighteen background characteristics, twelve were associated ($P < 0.15$) with the PCQ-Infertility total score. Moreover, the interactions between three background characteristics (ethnicity, duration of relationship and treatment type) and gender were associated with the PCQ-Infertility total score. These results from univariate analysis are shown in table I, column 3. Due to collinearity ($p = 0.818$), the couple characteristic 'median duration of infertility' was selected at the expense of the couple characteristic 'median duration of fertility care experience'. As a result, eleven background characteristics and three interactions were selected as case-mix adjusters in the final multivariate analysis.

Table 3 describes the results of the multilevel multivariate regression analysis with manual backward elimination. The background characteristics 'professional emotional support', 'number of hospital visits per month' and 'visiting the hospital as a couple' had no statistically significant impact on any outcome variable and are therefore not presented ($p > 0.05$). Table 3 shows no significant difference in PCQ-Infertility total scores between women and their partners, when adjusted for age, ethnicity, actual life-time events, duration of relationship and treatment type. Furthermore, in two out of seven subscales significant differences within the infertile couple were found: the PCQ-Infertility subscale 'respect for patients

values' ($B = 0.133$; 95% CI = 0.066 – 0.201) and the subscale 'staff's competence' ($B = 0.266$; 95% CI = 0.072 – 0.460) were significantly higher scored by partners than by women.

Table 1

Patient and couple characteristics and their association with PCQ-Infertility total score in univariate analysis

Patient characteristics	Women n=696	Men n=520	Univariate analysis
Median age (<i>years, range</i>)	33.0 (21-44)	35.0 (25-57)	<0.01*
Dutch ethnic background (%)	86.8	91.3	<0.01*/^
High level of education ^a (%)	50.0	48.9	0.346
Professional emotional support (%)	12.8	5.2	<0.01*
Medical history (%)	14.0	11.6	0.10*
Life-time events ^b (%)	10.7	9.2	0.10*
Being unemployed (%)	10.1	3.2	0.34
Reported ill at work last 3 months (%)	34.4	15.5	0.18
Median hospital visits per month (<i>nr, range</i>)	4.0 (0-17)	2.0 (0-21)	0.05*
Median travel time (<i>minutes, range</i>)	20.0 (2-161)	20.0 (2-120)	0.57
Couple characteristics			
Lesbian couples (%)	1.4		0.81
Mostly visiting hospital as couple ^c (%)	54.7		0.01*
Median duration of:			
relationship (<i>months, range</i>)	113.0 (14-358)		<0.01*/^
infertility (<i>months, range</i>)	34.0 (1-151)		<0.01*
fertility care experience (<i>months, range</i>)	18.0 (1 -131)		0.01*
Net monthly family income (<i>Euros, range</i>)	3500 (300-21.677)		0.18
Diagnosis (%)			
Male factor ^d / Female factor ^e / Other ^f	21.6 / 31.2 / 47.2		<0.01*
Treatment type (%)			
Non-ART ^g – ART ^h	48.7 / 51.3		<0.01*/^

^a High level of education = higher professional education or university.

^b Recent experienced (last three months) life time event, e.g. financial, work or relational problems.

^c Couples visiting the fertility clinic most of the time as a couple instead of the woman alone.

^d Low semen quality.

^e Irregular ovulation, polycystic ovary syndrome, tubal factor, endometriosis, mucus hostility

^f E.g. both male and female infertility diagnosis found, or unexplained infertility.

^g Non-ART included ovulation induction and intrauterine insemination with or without controlled ovarian stimulation.

^h Assisted reproductive technology (ART), encompassed IVF, IVM, ICSI, cryopreservation and testicular sperm extraction.

* Characteristics associated with PCQ-Infertility total score ($p < 0.15$) and therefore allowed in multivariate analysis.

^ Interactions between these characteristics and gender were significantly associated ($p < 0.15$) with the PCQ-Infertility total score.

Table 2**Median (range) scores PCQ-Infertility stratified by women and partners**

	Women	Partners
PCQ- Infertility total (0-3)	2.23 (0.50 – 2.98)	2.30 (0.56 – 2.98)
Accessibility of care	2.50 (0.00 – 3.00)	3.00 (0.00 – 3.00)
Information provision	2.18 (0.00 – 3.00)	2.27 (0.00 – 3.00)
Communication	2.67 (0.14 – 3.00)	2.71 (0.14 – 3.00)
Respect for patients' values	2.00 (0.00 – 3.00)	2.17 (0.00 – 3.00)
Continuity and transition of care	2.33 (0.00 – 3.00)	2.42 (0.00 – 3.00)
Patient involvement	1.79 (0.14 – 3.00)	1.86 (0.14 – 3.00)
Staff's competence	2.50 (0.67 – 3.00)	2.50 (0.50 – 3.00)

Discussion

This study shows that infertile women and their partners evaluate their overall experiences with patient-centred fertility care comparable, with only small differences. This is an important finding as patient-centredness of fertility care is a significant dimension of quality of care and needs improvement.^{2,12} Previously, studies often focused on the women of the infertile couple only or included the infertile couple as a whole. In our research, we have given a separate voice to the infertile partner as well.

It is interesting how these comparable experiences within the infertile couple can be more understood. Of course, both women and partners are in fact equally affected by the unfulfilled desire for a child.¹⁹ This is supported by similar overall

levels of QoL found in both partners of the infertile couple.¹⁷ The relation between the findings about QoL and patients' experiences with fertility care was studied by Aarts *et al.*¹⁰, showing a significant association between patient-centredness in fertility care and the patients' QoL, anxiety and depression.¹⁰ Apparently, women and partners having equal levels of QoL, report similar experiences with patient-centred fertility care. As we are discussing cross-sectional studies^{10,17}, associations can also be shown the other way around: women and their partners reporting similar experiences with patient-centred fertility care, have equal levels of QoL. Most importantly for our study is the understanding that next to equal levels of QoL, also comparable levels of patient-centred fertility care are reported within the infertile couple. This is especially interesting in the area of fertility care, as it has been shown that couple's agreement increases the ability to manage stressful

Table 3
Multilevel multivariate analyses; differences between women and partners with case-mix adjustment

Characteristics	PCQ total	Accessibility of care	Information provision	Communication	Respect for patients' values	Continuity and transition of care	Patient involvement	Staff's competence
Intercept	1.94 (1.75–2.21)	2.15 (1.96–2.33)	2.06 (1.90–2.21)	2.06 (1.82–2.31)	1.66 (1.33–1.98)	1.71 (1.61–1.81)	1.74 (1.42–2.06)	2.06 (1.86–2.26)
PARTNERS vs. WOMEN	-	-	-	-	0.13^a (0.07–0.20)	-	0.27 (0.07–0.46)	-
Age (years)	0.01 (0.00–0.01)	-	-	0.01 (0.00–0.01)	0.01 (0.00–0.02)	-	0.01 (0.00–0.02)	0.01 (0.00–0.01)
Ethnicity	0.09 (0.02–0.15)	-	0.12 (0.03–0.22)	0.134 (0.05–0.22)	0.16 (0.03–0.28)	-	0.18 (0.05–0.31)	0.09 (0.02–0.16)
Dutch vs. non-Dutch	-	-	-	-	-	-	-0.21 (-0.41–0.01)	-
Ethnicity*gender	-	-	-	-	-	-	0.10 (0.01–0.20)	0.08 (0.01–0.14)
Other medical treatment	-	0.17 (0.03–0.31)	0.13 (0.05–0.22)	-	-	-	-	-
Life-time events	-0.07 (-0.14– -0.01)	-	-0.13 (-0.23– -0.04)	-	-	-	-	-
Duration relationship (years)	0.01 (0.00–0.02)	-	-	0.01 (0.01–0.02)	-	0.01 (0.00–0.02)	-	0.01 (0.00–0.02)
Duration relationship*gender	-	0.02 (0.00–0.05)	-	-	-	-	-	-
Duration infertility (months)	-	-	0.00 (0.00–0.00)	-	-	-	-	-
Diagnosis	-	-	0.037 (0.01–0.22)	-	-	-	-	-
Male vs. Other	-	-	-	-	-	-	-	-
Treatment type	-0.24 (-0.30– -0.18)	-	-0.58 (-0.66– -0.50)	-0.15 ^b (-0.23– -0.07)	-0.44 (-0.53– -0.34)	-	-0.13 (-0.23– -0.03)	-0.07 (-0.14– -0.00)
Non-ART vs. ART	-	-	-	-	-	-	-0.12 (-0.24– -0.01)	-0.08 (-0.14– -0.02)
Treatment type*gender	-	-	-	-	-	-	-	-

Unstandardized coefficients with 95% confidence intervals ($p < 0.05$) are demonstrated here. ART = Assisted reproductive technology

^a Example 1: Partners had a 0.133-point higher mean score (i.e. more positive experiences) for the dimension 'Respect for patients' values' compared to their women, when adjusted for age, ethnicity and treatment type.

^b Example 2: Patients receiving non-ART treatments had a 0.151-point lower mean score (i.e. more negative experiences) for the dimension 'Communication' compared to patients receiving ART treatments, when adjusted for age, ethnicity, and duration of the relationship.

events, including the experience of infertility.³⁶ Moreover, our results can be of use in future studies about patients' experiences with fertility care. Including only one member of the infertile couple in these studies might be sufficient, as experiences within the couple are nominally comparable. Finally, our results should be taken into consideration when developing an improvement strategy for more patient-centred fertility care.

Although the results mentioned before count for the overall level of patient-centredness, differences were found on two subscales of patient-centred care. Partners reported significantly better experiences at the subscales 'Respect for patients' values' and 'Staff's competence' (4.4% and 7.5% better, respectively). Whether these differences are clinically relevant is debatable, as methods to determine the minimal clinically important difference (MCID) are never studied at the level of patient-centred care at all.^{37,38} However, if we do consider its relevance for daily practice, we should put these results in a broader perspective. In contrast to our study, no differences in patients satisfaction were found between infertile women and partners in two other studies^{14,26}, and one study reported even higher satisfaction rates of women compared to partners.²¹ As these studies used the more subjective and general outcome measure 'patient satisfaction'^{27,28} and did not determine differences *within* the infertile couple¹⁷, these results are scarcely comparable to our research. Based on our results, we can state that both members of an infertile couple are merely in agreement about their experiences with fertility care, but the small differences within the couples underline the uniqueness of a person and should always be taken into account in daily practice.

The main strengths of our study are the large randomly sampled diverse study population, the inclusion of infertile partners as a whole and the presentation of paired results. This methodology enables us to draw conclusions about the couples' experiences instead of only individual experiences, being very important in a fertility care setting.^{17,18} In addition, it is shown that patient-centredness relates to different background variables.^{21,29,33-35} Therefore, controlling for more than ten different, related patient en couple characteristics enhances our study results. To the best of our knowledge, this is the first study evaluating the level of patient-centred fertility care within the infertile couple.

Some potential weaknesses of our study should also be mentioned. First, the response rate differed substantially between women and partners. Because only 41% of all partners completed the questionnaire, our results will be partially influenced by selection bias. This is unfortunate, but conform the trend of the last 25 years, showing declining response rates of especially men in all health-care areas.³⁹⁻⁴¹ As the response of our study still included more than 500 Dutch partners

from all regions in the Netherlands, we assume that representativeness of Dutch infertile partners is ensured. Moreover, additional analysis showed that couples of which only the woman participated in the study ('incomplete couples'), only rarely visited the clinic as a couple. Partners who did complete the PCQ-Infertility are especially those capable to evaluate fertility care, because they visited the clinic more frequently. Second, now that we have the knowledge that both members of the infertile couple *report* their care experiences equally, does not mean they also *experience* it equally. It is plausible that men experience fertility care somewhat different than their women as they do not undergo the treatment physically and most often do not attend all meetings in the clinic. Nevertheless, the way they report these experiences is equal to their women's reporting. This should be taken into account when interpreting the results of our study. Third, as validation of the PCQ-Infertility questionnaire was performed on the infertile couple as a whole, our PCQ-Infertility scores could not be compared to those determined in the validation study.²⁹ To achieve this, additional validation of the PCQ-Infertility in women and partners separately is warranted. It would even be a suggestion for further research to develop an additional instrument focused only on partners in which gender-specific questions could be incorporated. It is shown in both fertility and general literature that the content of such a questionnaire differs from a questionnaire that focuses on women only.^{42,43} Fourth, because the PCQ-Infertility questionnaire has been validated in the Netherlands, our results are only applicable to the Dutch infertile population. As it is already suggested by Dancet *et al.* that patients across Europe have similar views on patient-centred care²², an international questionnaire is expected not to differ considerably from the PCQ-Infertility. Nevertheless, further research is essential before this statement can be underlined or rejected.

In summary, this study stressed out that not only infertile women, but also their partners are important care consumers, capable of evaluating their experiences with fertility care. Our results showed that infertile women and their partners evaluate their overall experiences with patient-centred fertility care equally, but small differences at the subscale levels exist. These results can be used when we aim at the improvement of patient-centred fertility care, one of the core dimensions of quality of care.

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"WE WILL GET YOU PREGNANT, LADY!" THESE WERE LITERALLY THE WORDS OF THE DOCTOR WHO WOULD MAKE SURE THAT I GOT WHAT I WANTED: A BABY. OF COURSE, I KNEW THAT THE CHANCE TO ACHIEVE PREGNANCY WAS FAR FROM GUARANTEED, BUT IT USED TO SOUND LIKE: "PLEASE, DO NOT THINK TOO MUCH ABOUT IT. YOUR GYNÁECOLOGY WILL MAKE SURE THAT IT WILL ALL TURN OUT WELL IN THE END." NO, THIS WAS DEFINITELY NOT WHAT I EXPECTED FROM A PATIENT-CENTRED CARE? I CAN ANSWER THIS QUESTION WITH A CATEGORICAL NO. MY HUSBAND AND I EXPERIENCED DURING THE FIVE YEARS THAT WE WERE WAITING FOR A CHILD DURING THESE YEARS, WE WENT THROUGH DIFFERENT POSITIVE AND NEGATIVE EXPERIENCES. TO MAKE IT MORE UNDERSTANDABLE HOW IT IS TO BE A PATIENT WITH INFERTILITY, I WILL SHARE SOME OF MY EXPERIENCES. AFTER I HAD UNDERGONE A LAPAROSCOPY TO FIGURE OUT WHY I WASN'T GETTING PREGNANT, A NEW APPOINTMENT WITHIN TWO WEEKS TO START UP A NEW TREATMENT WAS SURPRISINGLY ANSWERED: 'THIS MUST BE A MISTAKE, BECAUSE IT'S TOO EARLY AFTER SURGERY. OBVIOUSLY, YOUR BODY NEEDS MORE TIME TO RECOVER.' THAT WAS REALLY WHAT THE DOCTOR HAD TOLD ME. BUT BEFORE I COULD GO HOME, MY COLLEAGUE, AGAIN, SHE ONLY CONFIRMED WHAT HER COLLEAGUE HAD SAID. I HAD TO RETURN WITHIN TWO WEEKS TO CONTINUE MY TREATMENT (AND I HAD TO TALK TO THE SECRETARIES, WHO WERE ALSO FIRM IN THEIR STATEMENTS. I COULD NOT GO HOME. THERE WAS NO PROBLEM TO SEE THE DOCTOR AND THERE WAS NOTHING WRONG WITH ME. I WAS VERY INSECURE AND HAD STRESSED ME OUT, WHICH OBVIOUSLY OFTEN HAD TO SIT NEXT TO PATIENTS WHO WERE ALREADY PREGNANT AND TALKING ABOUT THE PROGRESS OF THEIR PREGNANCIES TOGETHER. THAT'S GOOD FOR INFERTILITY. IT WAS VERY HARD FOR ME TO SEE ALL THESE BIG BELLYS. THE DOCTOR ASKED ME TO RETURN TO THE WAITING ROOM FOR A FEW MORE MONTHS. THERE I WAS, SITTING NEXT TO A MOTHER WITH A TWO-YEAR OLD CHILD. I FELT I WANTED TO PUT MYSELF IN HER SHOES AND FELT REALLY MISERABLE. MY OWN EXPERIENCE WAS NOT REALLY IMPRESSIVE. FOR EXAMPLE, IT HAPPENED SEVERAL TIMES THAT I HAD AN APPOINTMENT. OBVIOUSLY, THE DOCTOR WAS NOT AWARE OF THE FACT THAT I HAD READ MY MEDICAL RECORD BEFORE I ENTERED THE ROOM. ALSO, THE INFORMATION WAS CONTRADICTORY. IT SEEMED LIKE ALL DOCTORS HANDLED OUR CASE DIFFERENTLY. IT SCARED ME A LITTLE BIT, AS I ALREADY FELT PSYCHOLOGICAL PRESSURE. I FELT THAT MY DOCTORS WERE ALL POINTING IN THE SAME DIRECTION. I FELT THAT OUR OWN DOCTOR SHOULD NEVER HAVE INTRODUCED THE IVF TREATMENT OPTIONS. VERY CONFUSING, AS WE DID NOT KNOW WHAT THE NEW TREATMENT I READ ABOUT IN A MAGAZINE. OUR DOCTOR HAD SAID THAT OUR HOSPITAL, WHILE EXACTLY THE OPPOSITE WAS TRUE ACCORDING TO THE CRITERIA ELIGIBLE FOR THIS TREATMENT BEFORE. EVENTUALLY, I WAS TOLD THAT I WAS BEING REFERRED TO ANOTHER HOSPITAL. MY HUSBAND AND I WENT TO AN ULTRASOUND CHECK-UP. A LOT OF SMALL FOLLICLES WERE VISIBLE. THE DOCTOR TOLD ME, BUT MY DOCTOR JUST SAID: 'YOUR OVARY LOOKS FINE, BUT THIS IS NOT WHAT YOU NEED OF COURSE!' WELL, THAT WASN'T THE ANSWER I WOULD LIKE TO SHARE, IS ABOUT MY ADMIS-
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CHAPTER 4

DIFFERENCES IN QUALITY OF LIFE AND EMOTIONAL STATUS BETWEEN INFERTILE WOMEN AND THEIR PARTNERS

Abstract

Background

The psychological impact of infertility in patients negatively affects their quality of life (QoL) and is also related to increased discontinuation of treatment. Moreover, psychological factors might positively affect pregnancy rates. However, it is still unclear if differences in QoL and emotional status exist between infertile women and their partners. So far, research mainly focused on generic instruments to measure patients' QoL in the area of fertility care. The main aim of this study is to explore whether QoL and the risk factors for emotional problems during and after treatment of infertile women differ from their partners.

Methods

A cross-sectional study of infertile couples within 32 Dutch fertility clinics. We included infertile women and their partners under any treatment and at any stage of treatment. Per clinic, 25–75 patients were randomly selected depending on clinic size. In total, 1620 women and their partners were invited separately to complete the FertiQoL and SCREENIVF questionnaires to measure their level of QoL and risk factors for emotional problems during and after treatment, respectively.

Results

A total of 946 women (response rate 58%) and 670 partners (response rate 41%) completed the questionnaire set. As 250 women and 150 partners were already pregnant, questionnaires from 696 women and 520 partners could be analysed. Women scored significantly lower on the FertiQoL total scores ($B = -6.31$; 95% confidence interval (CI) = -7.63 – 4.98) and three of the FertiQoL subscales (Emotional, Mind–Body and Social) than their partners, indicating lower QoL. Scores on the SCREENIVF questionnaire were significantly higher for women ($B = 0.22$; 95% CI = 0.06 – 0.38), indicating that women are more at risk for developing emotional problems (and these factors differed from those of their partners) during and after fertility treatment than their partners.

Discussion

Women have lower levels of fertility-related QoL, and more and differing risk factors for emotional problems during and after treatment than their partners. Although the number of participants is high ($n=1216$), the relatively low response rate, especially for partners (41%), may have influenced the results through selection bias. An analysis of non-responders could not be performed. The FertiQoL and SCREENIVF questionnaires, which have been validated only in women starting a first IVF cycle, should also be validated by studying partners. In addition, the SCREENIVF questionnaire has been validated in Dutch women only and further research in an international setting is

required. Our study results represent the Dutch infertile population as more than one-third of all Dutch clinics participated in the study. As the FertiQoL questionnaire is an internationally validated questionnaire already, these results can be put in a more broader and international perspective.

Introduction

Paying attention to the emotional burden of infertility is increasingly recognized in recent years.^{1,2} To understand the seriousness of patients' emotional problems in fertility care, the emotional status of infertile patients has been studied frequently. As a result, being infertile and undergoing fertility treatments have been found to affect patients' quality of life (QoL)^{1,3}, which may be seen in terms of impairment in psychosocial well-being, sexual satisfaction and marital relationship.^{1,4-6} Moreover, the stigmatizing character of infertility hinders patients talking about their problem, resulting in a lack of social support.^{7,8} Further, unsuccessful treatment cycles raise patients' levels of anxiety and depression¹ and even increase a woman's risk of suicide.⁹ All these psychological factors associated with infertility may influence patients' decisions to discontinue treatment prematurely^{2,10,11} and might lower their chances to achieve pregnancy.¹²⁻¹⁴ Obviously, psychological interventions are important for infertile patients in order to improve their mental health, decrease drop-out rates and possibly increase pregnancy rates.

Infertility is a shared condition, including a woman and her partner, therefore both members of the infertile couple should be studied individually before an accurate design for psychological interventions can be developed. Many studies that included both members of the infertile couple found differences in psychological responses to infertility, in which women appeared to experience more distress than partners.^{3,6,15-19} However, several other studies reported similar levels of QoL and distress in both infertile partners.²⁰⁻²³ Considering these mixed findings, more specific and clear research is needed to explore the emotional status of both members of the infertile couple. Moreover, most studies exploring gender differences in fertility care used generic instruments to measure patients' QoL or levels of distress.²⁴⁻²⁶ It is suggested that these standardized generic instruments are unable to easily detect differences between infertile women and their partners, as they do not represent all the unique problems of patients experiencing infertility.^{26,27} The use of a disease-specific instrument, such as the FertiQoL questionnaire (measuring patient QoL)²⁸ would be more valuable for this study purpose. Also the SCREENIVF questionnaire (identifying risk factors for emotional problems during and after treatment) could be of use, as it combines parts of both generic and disease-specific instruments.²⁷

The aim of this study is to explore the level of QoL and risk factors for emotional problems during and after treatment for both members of the infertile couple, using the FertiQoL and SCREENIVF questionnaires, respectively. A significant correlation between the results of both questionnaires for women has already been suggested by Aarts *et al.*²⁹ Because it is known that women and their partners use different coping strategies during fertility care²², we wanted to determine

these correlations in our study as well as provide more insight into the possible differences between women and partners. Therefore, we had three different study questions: (i) What is the difference in QoL between infertile women and their partners, measured with the FertiQoL questionnaire? (ii) Do infertile women and their partners have different risk factors for emotional problems during and after treatment, as measured with the SCREENIVF questionnaire? (iii) What is the correlation between the results of the FertiQoL and SCREENIVF questionnaires for infertile women and partners separately?

Materials and Methods

Setting and study design

This cross-sectional study was nested within of a large RCT (Clinicaltrials.gov NCT01481064), aimed at improving the level of patient-centredness of Dutch fertility care.³⁰ During the baseline measurement of this trial, we collected data on patients' QoL and risk factors for emotional problems during and after treatment. More than one-third of all Dutch clinics (i.e. 32 clinics) participated in the study.

Patient population

This study was performed in a patient group under treatment in 1 of 32 participating Dutch clinics. Clinics extracted the address files of all patients (i.e. both heterosexual and lesbian couples) who underwent at least one cycle of assisted reproduction treatment (e.g. ovulation induction, intrauterine insemination, IVF and ICSI treatment) in their clinics in the last 3 months (spring–summer 2011) from the Dutch coding system for medical diagnosis and treatment.³¹ All patient data were entered in a database and duplicate entries were removed. Subsequently, a computerized random sample was taken, including 25 patients for small clinics, 50 patients for medium sized clinics and 75 patients for large IVF clinics. Both members of the couple were invited to participate in the study individually. A total of 1620 questionnaires were sent to couples: one to the woman, one to her partner. Pregnant women and partners ($n=400$) were excluded from analyses, as most questions were no longer applicable then.

Ethical approval

The institutional ethics committee of Radboud University Nijmegen Medical Centre provided ethical approval for this research to proceed (CMO nr 2011/034). Informed consent was not necessary for this study.

Data collection

We sent an invitation letter to the women and partners of the selected couples in which they were invited to complete their own online questionnaire set, accessible by a personal code. Participation was voluntary and anonymous. A reminder was sent after two weeks and non-responders had an additional option to complete a paper version of the questionnaire sent another three weeks later.

Questionnaires

The first part of the questionnaire set consisted of 17 background questions. These questions were selected as potential case-mix adjusters, based on the literature as possibly being associated with patients' QoL or distress.^{1,3,6,11} Background questions included general questions (e.g. age, ethnicity), questions about patients' emotional status (e.g. seeking professional emotional support in the last 3 months, adverse life-time events) and questions regarding past and current fertility treatments (e.g. duration of infertility, diagnostics category, type of treatment). The second and third part of the questionnaire set consisted of the FertiQoL and SCREENIVF questionnaires.

FertiQoL

The internationally developed and validated FertiQoL questionnaire consists of two general items (i.e. 'How would you rate your health?' and 'Are you satisfied with your quality of life?') and two modules measuring QoL (the Core module and the optional Treatment module). In the validation study, the questionnaire has shown to be reliable with Cronbach reliability statistics ranging from 0.72 to 0.92.²⁸ The Core module involves 24 fertility-specific items covering four subscales (i.e. six items per subscale); Mind-Body (e.g. 'Do you feel drained or worn out because of fertility problems?'), Emotional (e.g. 'Do your fertility problems cause feelings of jealousy and resentment?'), Relational (e.g. 'Have fertility problems had a negative impact on your relationship with your partner') and Social (e.g. 'Are you satisfied with the support you receive from friends with regard to your fertility problems?'). The optional Treatment module assesses QoL related to the fertility treatment itself. In this study, the Dutch version of the FertiQoL Core module was used. A higher score on the total FertiQoL scale or one of the subscales (range 0–100) indicates better QoL.²⁸

SCREENIVF

The recently developed SCREENIVF questionnaire is a screening instrument and consists of 31 questions covering five emotional maladjustment scales (i.e. five predefined risk factors for increased emotional problems during and after fertility

treatment). These scales include: Anxiety (seven items, e.g. 'Worrying thoughts go through my mind'), Depression (seven items, e.g. 'I have lost interest in my appearance'), Helplessness (six items, e.g. 'My infertility problem limits me in everything that is important to me'), Acceptance regarding fertility problems (six items, e.g. 'I can cope effectively with my infertility problems') and perceived social support (five items, e.g. 'When I feel sad, there is someone I can share my grief with').²⁷ The assessments of anxiety, depression and perceived social support are based on generic instruments [i.e. Hospital Anxiety and Depression Scale³² and Inventory of Social Involvement]³³; the assessments of helplessness and acceptance are based on a fertility-specific instrument (i.e. Illness Cognition Questionnaire).^{16,34} In previous studies, all scales showed good Cronbach reliability scores, ranging from 0.82 to 0.92.²⁷ The five scales have individual cut-off values to determine whether a patient is at risk at this specific domain. For anxiety and depression, the cut-off value is 9 and above. The cut-off score for helplessness is 14 and above, it is 11 and less for acceptance and 15 and less for social support (based on 1 SD above or below the mean scores of IVF patients in a previous study).²⁷ Based on these five subscales, total SCREENIVF scores range from 0 to 5, indicating how many risk factors for increased emotional problems during and after fertility treatment are present.²⁷ Moreover, a SCREENIVF at risk score (%) can be calculated, indicating the percentage of patients having at least one risk factor for emotional maladjustment during and after treatment.

Statistical analysis

We described all median FertiQoL and SCREENIVF scores of women and partners and compared them using the *t*-test for independent samples (FertiQoL total and subscale scores and SCREENIVF total scores) and chi-square tests (SCREENIVF at risk scores).

Subsequently, we performed multiple univariate linear regression analyses to identify potential case-mix adjusters for our main analysis. All 17 background characteristics were included separately and characteristics with $P < 0.15$ in the univariate analyses were selected as case-mix adjusters and incorporated within the multivariate analyses.

We performed our main analysis from a dyadic perspective with the infertile couple as the unit of analyses. By performing this kind of analyses, we were able to evaluate intra-couple differences, which is a more powerful methodology than comparing a group of infertile women and partners separately.^{22,23} We structured the database so that each line contained data for one individual, with a variable included that defined the couple. Then, a multilevel multivariate regression analysis with manual backward elimination was carried out with the individual

(level 1) nested within the couple (level 2). The FertiQoL total and subscale scores and the SCREENIVF scores acted as the dependent variables, being a women or a partner acted as the independent variable. Also the selected case-mix adjusters were included in this final analysis. Furthermore, we determined the explained variance by calculating R^2 , indicating the percentage of variance in FertiQoL and SCREENIVF scores that is attributable to patients' gender (women and partners).

Finally, we explored the correlation between the FertiQoL and SCREENIVF questionnaires by first calculating mean FertiQoL scores for both women and partners who had at least one risk factor in the SCREENIVF questionnaire (i.e. being 'at risk') and comparing them using an independent samples t -test. Moreover, we performed correlation analyses with Spearman's rho using the FertiQoL and SCREENIVF total scores for both women and partners separately. Significance for all multilevel analyses was set at $P < 0.05$. Analyses were performed using the Statistical Package for the Social Sciences (version 18.0 for Windows®, SPSS Inc., Chicago, IL, USA).

Results

A total of 946 women (response rate 58%) and 670 partners (response rate 41%) completed the questionnaire set. After removing the questionnaires from pregnant women and their partners ($n = 400$), 1216 questionnaires were eligible for analyses: 696 from the women and 520 from the partners. Our final sample therefore contained fewer partners than women, but we corrected for the incomplete couples in our analysis.

Table 1 shows the background characteristics stratified by women and partners, including the results from the univariate analyses. All patient characteristics ($n = 10$) and the couple characteristic 'Diagnosis' (i.e. male infertility, female infertility, both male and female infertility, unexplained infertility and other) were associated ($P < 0.15$) with both the FertiQoL total scores and the SCREENIVF scores. Because only the diagnostic category 'unexplained infertility' was significantly related to both questionnaires, we dichotomized this characteristic into 'unexplained infertility' versus 'no unexplained infertility', as shown in Table 1. Furthermore, the couple characteristics 'Treatment' was also related to the FertiQoL scores.

Table 2 presents the questionnaires' total and subscale scores. At the SCREENIVF questionnaire, 63.8% of women ($n = 385$) and 45.6% of partners ($n = 191$) had at least one risk factor for emotional problems ($P < 0.01$). Women were significantly more at risk on the subscales 'Anxiety', 'Depression', 'Helplessness' and 'Acceptance' than their partners. About one-third of all women and partners were at risk at the subscale 'Lack of social support', but no significant differences

were found within the infertile couple.

The results from the multilevel multivariate regression analysis are presented in Table 3. After case-mix adjustment, partners had a significantly higher score on the FertiQoL total scale and the subscales 'Emotional', 'Mind-Body' and 'Social' than the women (i.e. better QoL). On the 'Relational' subscale, no differences were found within the couple. Scores on the SCREENIVF questionnaire were significantly higher for women after case-mix adjustment, indicating that women had more risk factors for emotional problems during and after fertility treatment than their partners. Table 3 shows that 28% of the variance in FertiQoL total scores was attributable to patient gender. For the SCREENIVF scores, this variance was 16%.

Further, when focusing only on women and partners having at least one risk factor on the SCREENIVF questionnaire, women had a lower FertiQoL total score than partners, which was a statistically significant difference (mean score for women: 63.3, SD 12.6; and partners: 71.6, SD 12.0; P -value ≤ 0.001). Finally, the Spearman's rho correlation between FertiQoL and SCREENIVF scores was -0.73 for women and -0.60 for partners.

Discussion

The present study showed that infertile women had significantly lower levels of QoL than their partners. Also three of the four FertiQoL subscales were significantly different within the infertile couple, with women having lower scores on all subscales. Moreover, women had more and different risk factors for developing emotional problems during and after treatment than their partners. Obviously, infertility impacts differently on women than on partners, which is an important finding, as previous studies showed incompatible results about the emotional status of infertile women and their partners. With the use of two recently developed, validated and disease-specific instruments, we have provided more insight into the impact of infertility on QoL and the emotional burden of infertility within the couple.

Only one other study examined infertile couples' QoL from a dyadic perspective, finding no differences within the infertile couple.²³ A plausible explanation for this difference is the use of a fertility-specific questionnaire (i.e. FertiQoL) in our study, instead of the generic QoL assessment instrument (i.e. WHOQOL-BREF) used by Chachamovich *et al.*²³ As we aimed at detecting QoL differences between women and partners in the setting of fertility care, the results of our study may seem more relevant to this specific area of health care. The R^2 values that we found in our study underline this, as a significant proportion of variance in

Table 1

Characteristics of infertile patients and couples and their association with FertiQoL and SCREENIVF scores in univariate analyses.

Individual patient characteristics	Women (n = 696)	Partners (n = 520)	Univariate analyses	
			FertiQoL Beta (95% CI)	SCREENIVF Beta (95% CI)
Age (years, range)	33.0 (21–44)	35.0 (25–57)	0.71 (0.57–0.86)	-0.06 (-0.08–0.05)
Dutch ethnic background (%)	86.8	91.3	4.33 (1.89–6.78)	-0.42 (-0.68–0.17)
High level of education ^a (%)	50.0	48.9	1.60 (0.03–3.16)	-0.24 (-0.40–0.07)
Professional emotional support ^b (%)	12.8	5.2	-12.30 (-14.86–9.74)	1.11 (0.84–1.37)
Current other medical treatment ^c (%)	14.0	11.6	-3.38 (-5.70–1.05)	0.26 (0.02–0.51)
Life-time events ^d (%)	10.7	9.2	-6.98 (-9.53–4.42)	0.63 (0.36–0.90)
Being unemployed (%)	10.1	3.2	-5.50 (-8.51–2.48)	0.45 (0.14–0.77)
Reported ill at work last 3 months (%)	34.4	15.5	-6.73 (-8.49–4.97)	0.50 (0.32–0.69)
Median hospital visits per month (nr, range)	4.0 (0–17)	2.0 (0–21)	-1.35 (-1.65–1.05)	0.11 (0.08–0.14)
Median travel time (minutes, range)	20.0 (2–161)	20.0 (2–120)	-0.06 (-0.11–0.01)	0.01 (0.00–0.01)
Couple characteristics				
Lesbian couples (%)	1.4		n.s.	n.s.
Duration of:				
-Relationship (months, range)	113.0 (14–358)		n.s.	n.s.
-Infertility (months, range)	34.0 (1–151)		n.s.	n.s.
-Fertility care experience (months, range)	18.0 (1–131)		n.s.	n.s.
Being childless (%)	74.9		n.s.	n.s.
Having previous abortions or EUP's ^e (%)	12.3		n.s.	n.s.
Net monthly family income (Euros, range)	3500 (300–10.833)		n.s.	n.s.
Diagnosis: Unexplained infertility/no unexplained infertility (%)	35.8 / 64.2		1.32 (-0.40–3.06)	-0.06 (-0.12–0.01)
Treatment: non-ART ^g /ART ^h (%)	48.7 / 51.3		-1.62 (-3.31–0.08)	n.s.

n.s. ($p > 0.15$) and therefore not included in multivariate regression analyses.

All other variables were taken up in the final multivariate analyses.

^a High level of education = higher professional education or university.

^b Recent professional emotional support by a psychologist (last 3 months).

^c Currently being under treatment for another medical problem.

^d Recently experienced (last 3 months) life-time event, e.g. financial, work or relational problems.

^e Extra uterine pregnancies.

^f No male and/or female infertility diagnosis was found.

^g Non-assisted reproduction with or without controlled ovarian stimulation and intrauterine insemination.

^h ART, encompassed IVF, in vitro maturation, ICSI, cryopreservation, and testicular sperm extraction.

Table 2**Unadjusted total and subscale scores of the FertiQoL and SCREENIVF questionnaires**

Questionnaires	Women (n = 696)	Partners (n = 520)	P-value
	Median (Range)	Median (Range)	
FertiQoL total score, median (range)	70.8 (14.6–96.9)	80.2 (35.4–100.0)	<0.01
Emotional	52.5 (0.0–100.0)	79.2 (8.3–100.0)	<0.01
Mind–Body	66.7 (0.0–100.0)	83.3 (29.2–100.0)	<0.01
Relational	79.2 (2.5–100.0)	79.2 (25.0–100.0)	n.s.
Social	75.0 (4.2–100.0)	83.3 (29.2–100.0)	<0.01
SCREENIVF total score, median (range)	1.0 (0.0–5.0)	0.0 (0.0–5.0)	<0.01
SCREENIVF patients at risk ^a , %	63.8	45.6	<0.01
Anxiety	27.4	11.1	<0.01
Depression	9.9	5.3	<0.01
Helplessness regarding infertility	34.2	12.6	<0.01
Lack of acceptance regarding fertility problems	31.2	12.8	<0.01
Lack of social support	33.0	36.0	n.s.

Differences were calculated using *t*-tests for independent samples and χ^2 tests for continuous and categorical variables.

^a Patients were identified as 'at risk' in case they were at risk on at least one of the five subscales.

FertiQoL and SCREENIVF scores was attributable to differences between women and their partners.

We found several interesting differences within the infertile couple that are worth discussing. First, partners reported higher scores on the FertiQoL 'Mind–body' subscale. This could be understood, knowing that most partners do not attend all visits, and in most of the cases do not have to undergo the treatments physically. By including more partners undergoing Percutaneous Epididymal Sperm Aspiration (PESA) or Testicular Sperm Extraction (TESE) in further research, this hypothesis could be supported or rejected. Secondly, differences at the 'Emotional' and 'Social' subscales might imply that women are affected emotionally in different ways by the stress of infertility compared with their partners. This corresponds to our findings on the SCREENIVF questionnaire, as women were vulnerable to more and other risk factors for emotional problems than their partners. Also other studies found similar results showing, for example, higher levels of anxiety and more depressive symptoms in women compared with men.^{18,35}

It would be valuable to understand why infertility impacts differently on women and partners. Peterson *et al.*^{22,36} mentioned the use of different coping strategies as a possible explanation. Women appeared to use greater amounts of confrontative coping, accepting responsibility and escape or avoidance coping, while partners tend to use more coping techniques, such as distancing, self-controlling and

planful problem-solving. Moreover, a partner's coping pattern influences the woman's ability to cope with the infertility and vice versa.^{22,36,37} In our study, we showed different correlations between the FertiQoL and SCREENIVF scores for women and partners, which could also indicate why women and partners differ. Because this correlation was slightly stronger in women than in partners, we might conclude that more risk factors for emotional problems in women (i.e. being at risk in the SCREENIVF) are related to the high impact of their infertility problem (i.e. low FertiQoL scores), while partners might be influenced by several other factors that were not included in the questionnaires (e.g. work-related problems, sexual problems). This is underlined by our additional analysis, showing lower FertiQoL scores in women having at least one risk factor on the SCREENIVF questionnaire, compared with partners being at risk for emotional problems. Also Wischmann *et al.*¹⁹ found similar results, as infertile women mainly suffered from childlessness and depression. However, distress in partners was mainly indicated by dissatisfaction with the partnership and sexuality.¹⁹ Based on our results, we might state that infertile women experience higher levels of distress than their partners. Moreover, women's distress could be linked more to fertility-related problems than distress in partners, which should be taken into account in daily practice.

In fertility care, the professionals' decision as to whether a patient could benefit from additional psychosocial support is mainly based on 'gut feeling'.²⁷ To help them in this process, cut-off values of instruments such as the FertiQoL and SCREENIVF questionnaires are necessary to select especially those patients that are emotionally more affected by their fertility problem. The results of our study show that these cut-off values would differ remarkably between women and partners, underlining the necessity of validating both questionnaires for infertile partners as well. It would even be more valuable to develop an additional instrument for partners. It is shown in both the fertility and general literature that the content of such a questionnaire differs from a questionnaire that focuses on women only.^{26,38} For example, the content of a questionnaire for men experiencing infertility due to a male factor consisted of many questions about 'sexual relationship' and 'gender identity'.²⁶ Hence, the risk of developing emotional problems during and after treatment can be determined for both members of the infertile couple appropriately. This enables fertility care professionals to identify women and partners who could benefit from additional psychosocial support and to provide a more tailored psychosocial support.

This study has several strengths. First, the large randomly sampled diverse study population ensures representativeness of the Dutch infertile population. Secondly, the presentation of paired results enables us to draw conclusions about

Table 3

Multilevel multivariate analyses; differences between women and partners with case-mix adjustment.

Characteristics	FertiQoL				SCREENIVF	
	Total score	Emotional	Mind-Body	Relational	Social	Total score
Intercept	50.95 (44.83 - 57.06)	36.73 (26.76 - 45.70)	39.05 (31.01 - 47.10)	76.99 (75.94 - 78.06)	57.75 (49.59 - 65.90)	3.41 (2.69 - 4.13)
PARNTERS vs. WOMEN	6.31 (4.98 - 7.63)	11.66 (9.50 - 13.81)	11.00 (9.12 - 12.87)	-	3.53 (1.76 - 5.29)	-0.22 (-0.38 - -0.06)
Age (yrs)	0.36 (0.21 - 0.51)	0.72 (0.48 - 0.96)	0.62 (0.42 - 0.83)	-	0.29 (0.09 - 0.49)	-0.04 (-0.06 - -0.03)
Dutch ethnicity	-	-	-	-	4.08 (1.38 - 6.78)	-0.30 (-0.55 - -0.05)
High level of education	-	-	-	-	-	-
Psychosocial support	-6.78 (-9.17 - -4.40)	-	-9.09 (-12.37 - -5.81)	-	-7.60 (-10.61 - -4.59)	0.72 (0.45 - 0.99)
Other medical treatment	-2.19 (-4.21 - -0.18)	-	-	-	-	-
Life-time events	-4.62 (-7.02 - -2.22)	-6.99 (-10.73 - -3.25)	-4.69 (-8.01 - -1.38)	-	-5.85 (-8.84 - -2.86)	0.44 (0.17 - 0.71)
Being unemployed	-	-	-	-	-	0.42 (0.10 - 0.74)
Reported ill at work	-2.30 (-3.87 - -0.73)	-2.97 (-5.46 - -0.48)	-5.44 (-7.62 - -3.26)	-	-	-
Median hospital visits (nr)	-0.49 (-0.79 - -0.20)	-	-0.96 (-1.37 - -0.55)	-	-0.55 (-0.93 - -0.17)	0.07 (0.04 - 0.11)
Median travel time (min)	-	-	-	-	-0.07 (-0.12 - -0.01)	-
Unexplained infertility	-	-4.37 (-6.90 - -1.84)	-	-	-2.65 (-4.65 - -0.47)	-
R²	0.28	0.25	0.35	-	0.12	0.16

Only statistically significant coefficients (B) with 95% CIs are demonstrated here. These coefficients describe the differences in FertiQoL or SCREENIVF scores between partners and women. It also indicates the direction of the associations. For example, partners had an 11.66 point higher score on the Emotional subscale of the FertiQoL than the women, when adjusted for age, life-time events, reported ill at work and unexplained infertility. Another example: partners had a 0.22 point lower score on the SCREENIVF questionnaire than the women, when adjusted for age, ethnicity, psychosocial support, life-time events, being unemployed and median hospital visits. R² = Explained variance; this represents the percentage of variance in the FertiQoL and SCREENIVF scores attributable to patients' gender (partners versus women).

the differences in emotional status within the infertile couple.^{22,23} This is especially important in a fertility care setting, as infertility is a shared condition involving both members of the couple. Thirdly, we included two measuring methods by using an entire disease-specific questionnaire (i.e. FertiQoL questionnaire) and a combined questionnaire of disease-specific and generic elements (i.e. SCREENIVF questionnaire). The disease-specific elements are necessary to include all the unique problems of patients experiencing infertility. The generic elements of the SCREENIVF questionnaire enable us to generalize our results to a broader patient population as well. In addition, it should be noted that the two questionnaires also have some overlap and could measure some comparable concepts, such as emotional or social problems. Aarts *et al.* already showed that the subscales of the FertiQoL questionnaire have a weak to moderate correlation with the anxiety and depression scales of the SCREENIVF questionnaire.²⁸

Some potential weaknesses of this study are also worth considering. First, the response rate differed substantially between women and partners. Because only 41% of all partners completed the questionnaire, our results may be partially influenced by selection bias. This is unfortunate but confirms the trend of the last 25 years, showing declining response rates, especially of men, in all healthcare areas.³⁹⁻⁴¹ As the response of our study still included more than 500 Dutch partners from all regions in the Netherlands, we assume that representativeness of Dutch infertile partners is ensured. Non-responder analyses would have provided additional information about the level and direction of the potential bias. Unfortunately, we did not have the data to perform this kind of analysis. Secondly, we used the FertiQoL and SCREENIVF questionnaire to study women and partners, while both instruments are only validated in women starting their first IVF treatment. Moreover, as we aimed to explore possible differences within the infertile couple, instead of determining 'cut-off values', the use of these questionnaires is justified for our research question. However, we still suggest validating these questionnaires for partners as well in further research. Thirdly, the percentages of patients at risk at the SCREENIVF questionnaire differed substantially from the results of van Dongen *et al.*⁴² We found 64% of the women and 46% of the partners to be at risk, compared with one-third of all patients (i.e. women and partners) in the previous study.⁴² The different patient populations may explain these differences, as Van Dongen *et al.* included patients who were about to start their first IVF/ICSI cycle, while our patients received different treatments in all different phases.⁴² It is already known that a woman's emotional response to IVF differs across the course of the treatment.¹⁶ Our results might point to a change, or even increase, on both women's and partners' emotional problems during treatment, which underlines the high psychosocial impact of infertility and its treatment as well as the need for adequate psychosocial support

in all treatment phases. In summary, infertile women have lower fertility-related levels of QoL than their partners. Moreover, women seem to be more at risk and have different risk factors for developing emotional problems during and after fertility treatment than their partners. This study showed that both members of the infertile couple are vulnerable to different sources of psychological stress, which underlines the importance of identifying risk factors for emotional problems for both members of the couple separately. Only then can infertile women and partners receive the tailored psychosocial support they need.

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"WE WILL GET YOU PREGNANT, LADY!" THESE WERE LITERALLY THE WORDS OF THE DOCTOR WHO WOULD MAKE SURE THAT I GOT WHAT I WANTED: A BABY. OF COURSE, I KNEW THAT THE CHANCE TO ACHIEVE PREGNANCY WAS FAR FROM GUARANTEED, BUT IT USED TO SOUND LIKE: "PLEASE, DO NOT THINK TOO MUCH ABOUT IT. YOUR GYNÁECOLOGY WILL MAKE SURE THAT IT WILL ALL TURN OUT WELL IN THE END." NO, THIS WAS DEFINITELY NOT WHAT I EXPECTED FROM A PATIENT-CENTRED CARE? I CAN ANSWER THIS QUESTION WITH A CATEGORICAL NO. MY HUSBAND AND I EXPERIENCED DURING THE FIVE YEARS THAT WE WERE WAITING FOR A CHILD DURING THESE YEARS, WE WENT THROUGH DIFFERENT POSITIVE AND NEGATIVE EXPERIENCES. TO MAKE IT MORE UNDERSTANDABLE HOW IT IS TO BE A PATIENT WITH INFERTILITY, I WILL SHARE SOME OF MY EXPERIENCES. AFTER I HAD UNDERGONE A LAPAROSCOPY TO FIGURE OUT WHY I WASN'T GETTING PREGNANT, A NEW APPOINTMENT WITHIN TWO WEEKS TO START UP A NEW TREATMENT WAS SURPRISINGLY ANSWERED: 'THIS MUST BE A MISTAKE, BECAUSE IT'S TOO EARLY AFTER SURGERY. OBVIOUSLY, YOUR BODY NEEDS MORE TIME TO RECOVER.' THAT WAS REALLY WHAT THE DOCTOR HAD TOLD ME. BUT BEFORE I COULD RETURN TO MY COLLEAGUE. AGAIN, SHE ONLY CONFIRMED WHAT HER COLLEAGUE HAD SAID. MY RETURN WITHIN TWO WEEKS TO CONTINUE MY TREATMENT (AND I HAD TO WAIT FOR THE SECRETARIES, WHO WERE ALSO FIRM IN THEIR STATEMENTS. I COULD NOT GO. THERE WAS NO PROBLEM TO SEE THE DOCTOR AND THERE WAS NOTHING WRONG WITH MY RESULTS. I WAS VERY INSECURE AND HAD STRESSED ME OUT, WHICH OBVIOUSLY OFTEN HAD TO SIT NEXT TO PATIENTS WHO WERE ALREADY PREGNANT AND WERE TALKING ABOUT THE PROGRESS OF THEIR PREGNANCIES TOGETHER. THAT'S GOOD FOR INFERTILITY. IT WAS VERY HARD FOR ME TO SEE ALL THESE BIG BELLYS. THE DOCTOR ASKED ME TO RETURN TO THE WAITING ROOM FOR A FEW MORE MONTHS. THERE I WAS, SITTING NEXT TO A MOTHER WITH A TWO-YEAR OLD CHILD. SHE WANTED TO PUT MYSELF IN HER SHOES AND FELT REALLY MISERABLE. MY OWN EXPERIENCE WAS NOT REALLY IMPRESSIVE. FOR EXAMPLE, IT HAPPENED SEVERAL TIMES THAT I DID NOT GET AN APPOINTMENT. OBVIOUSLY, THE DOCTOR WAS NOT AWARE OF THE FACT THAT I HAD TO READ MY MEDICAL RECORD BEFORE I ENTERED THE ROOM. ALSO, THE INFORMATION WAS CONTRADICTORY. IT SEEMED LIKE ALL DOCTORS HANDLED OUR CASE DIFFERENTLY. IT SCARED ME A LITTLE BIT, AS I ALREADY FELT PSYCHOLOGICAL PRESSURE. THAT MY DOCTORS WERE ALL POINTING IN THE SAME DIRECTION. I FELT THAT OUR OWN DOCTOR SHOULD NEVER HAVE INTRODUCED THE IVF TREATMENT OPTIONS. VERY CONFUSING, AS WE DID NOT KNOW WHAT THE BEST NEW TREATMENT I READ ABOUT IN A MAGAZINE. OUR DOCTOR HAD SAID THE OPPOSITE WAS TRUE ACCORDING TO THE RESEARCH. I WAS NOT ELIGIBLE FOR THIS TREATMENT BEFORE. EVENTUALLY, I WAS TOLD THAT I WAS. BY ANGELIQUE J.C.M. VAN DONGEN, MY HUSBAND AND I WENT TO THE ULTRASOUND CHECK-UP, A LOT OF SMALL FOLLICLES WERE VISIBLE. THAT'S A GOOD THING, BUT MY DOCTOR JUST SAID: 'IT LOOKS FINE, BUT THIS IS NOT WHAT YOU NEED OF COURSE!' WELL, THAT'S NOT WHAT I WOULD LIKE TO SHARE, IS ABOUT MY ADMIS- SION TO THE HOSPITAL DURING MY PREGNANCY. YES, WE FINALLY GOT PREGNANT AFTER FIVE YEARS. THEREFORE, IT WAS EVEN MORE STRIKING THAT THE DOCTOR ENTERED MY ROOM: 'IT IS VERY NICE AND QUIET ON THIS SECTION. I AM HERE TO HELP YOU. HE ASKED ME HOW I WAS DOING. I TOLD HIM I WAS 'ALLOWED' TO GO HOME, HE SAID. HE OBVIOUSLY THOUGHT THAT I WAS A PERFECT EXAMPLE OF 'TALKING ABOUT THE PATIENT', INSTEAD OF

ALEIDA G. HUPPELSCHOTEN

ANGELIQUE J.C.M. VAN DONGEN

ILSE C.P. PHILIPSE

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CHAPTER 5

PREDICTING DROPOUT IN FERTILITY CARE:

A LONGITUDINAL STUDY ON PATIENT-CENTREDNESS

Abstract

Background

In fertility care, a significant proportion of patients do not achieve pregnancy because they discontinue treatment prematurely. Many studies have tried to identify factors predicting dropout, showing incompatible results. However, these studies mainly focus on factors at the treatment and patient level, while clinic factors have received little attention. Therefore, our main aim was to study whether clinic factors, including patients' experiences with patient-centred care, are associated with dropout in fertility care.

Methods

This prospective, longitudinal study was nested within a large RCT, which aims to improve the level of patient-centredness of Dutch fertility care. Of the 1620 infertile women who were invited to participate, the baseline measurement of the study (T0) included 693 women who completed a questionnaire about their experiences with patient-centred fertility care. The follow-up of the patients was 1 year (T1). All included women suffered from infertility and were undergoing treatment in one of the 32 Dutch clinics involved in the trial. Levels of patient-centredness were determined using the Patient-Centredness Questionnaire-Infertility (PCQ-Infertility) at T0. Meanwhile, a professionals' questionnaire was used to gather additional information on characteristics of the clinic (e.g. the number of patients per year or the presence of a fertility nurse). After one year, at T1 measurement, patients completed a questionnaire on their current status in fertility care, including their main reason for discontinuation if applicable.

Results

A total of 693 non-pregnant women completed the questionnaire set at T0 and 534 women (77.1%) provided consent for follow-up. At T1 measurement, 434 women (81.3%) completed the questionnaire and 153 of these women (35.2%) continued treatment while 76 women (17.5%) dropped out. Another 175 women (40.3%) had achieved pregnancy and 30 patients (7.9%) were advised to discontinue treatment for medical reasons. Neither levels of patient-centredness nor the additional clinic characteristics differed significantly between dropouts and compliers. However, patients who did not receive assisted reproduction treatments (ART; e.g. underwent intrauterine inseminations) before they dropped out had significantly lower scores on the PCQ-Infertility subscale 'Respect for patients' values' than patients who continued their treatment [odds ratio (OR) 0.57; 95% confidence interval (CI) 0.34–0.95]. Patients who received ART and, subsequently, dropped out had higher scores on the PCQ-Infertility subscale 'Patient involvement' than those who continued treatment (OR 2.39; 95% CI 1.02–5.59).

Conclusions

The results of this study provide a better insight into those factors influencing dropout from the perspective of factors in the clinic itself. Although most clinic factors were not related to dropout, clinic factors might be of use when predicting dropout for specific patient groups, such as patients receiving ART and non-ART. Future research should involve an exploration of more specific predictors of dropout at the patient, treatment and clinic levels.

Introduction

A successful fertility treatment is something every infertile couple is striving for. Unfortunately, a significant proportion of couples do not achieve pregnancy because of medical factors, but also because they discontinue treatment prematurely. The exact number of patients dropping out of fertility treatment varies across European studies and ranges from 17 to 70%.¹⁻⁷ This wide range might be due to the conceptual issues around the definition of dropout and the methodological differences between studies.^{7,8} However, it still indicates that treatment dropout concerns many infertile patients. It is worrisome that these couples decide to give up their dream of becoming parents, because of the physical or psychological burden they encounter during treatment. Therefore, prognostic factors for dropping out should be identified to develop interventions, which target specifically those burdensome aspects of treatment.⁷⁻⁸

When considering the reasons why patients discontinue treatment, one could think of reasons related to the patients themselves (e.g. their well-being) or the kind of treatments they receive.⁸ Moreover, it might be expected that reasons related to the clinic itself, such as inadequate organization of care or poor communication skills of staff, influences patients' decisions to discontinue fertility treatment prematurely. This is supported by the literature where, for example, inadequate information provision and coordination of care have been identified as reasons for dropout.⁹ Also a lack of empathy by the staff, poor listening skills¹ and negative interactions with staff³ have been cited as reasons to discontinue treatment. Apparently, numerous clinic factors have been reported in connection with discontinuation⁸, but whether they could be used as a predictor of dropout has never been studied. It would be interesting to investigate this possible relationship through longitudinal research, as it shows us to what extent professionals could account for these factors in daily practice to prevent dropout.

To identify clinic factors as potential predictors of dropout, standard clinic characteristics could be studied (e.g. clinic size and presence of specialized fertility nurses). Furthermore, it would be valuable to ask infertile patients themselves about their experiences with fertility care in a clinic to identify relevant and predictive clinic factors for dropout. The recently developed and validated Patient-Centredness Questionnaire-Infertility (PCQ-Infertility) could be used for this goal, as it measures patient-centredness from the patients' perspective in seven different and concrete dimensions (e.g. accessibility of care, continuity and transition and professionals' competence).¹⁰ Van Empel *et al.* already showed that patients change clinics because they experience a lack of patient-centred care. Whether patients dropout treatment because of a lower level of patient-centred fertility care is unknown.¹¹

Therefore, the main aim of this study was to identify clinic factors, including patients' experiences with patient-centredness in their clinic, as potential predictors of dropout in fertility care, in a prospective manner. Furthermore, previous studies have shown that barriers to the uptake of treatment for dropout are common to all types of treatment, while others are type-specific.⁶⁻⁷ Because van Empel *et al.* found a significant association between treatment type [i.e. assisted reproduction treatment (ART) and non-ART] and patient-centred care¹², we wanted to study the relation between dropout and patient-centred care for these subgroups of patients as well.

Materials and Methods

Study design

This prospective longitudinal study was nested within a large RCT (Trial registration number: Clinicaltrials.gov NCT01481064), which aims to improve the level of patient centredness of Dutch fertility care.¹³ During the baseline measurement of this study (T0), patients completed a questionnaire on their experiences with patient-centred care. We used a questionnaire for professionals to gather additional clinic characteristics as potential predictors of dropout. One year later (T1), patients who gave consent for follow-up received a questionnaire on their current status in fertility care.

Setting

In the Netherlands, fertility care is provided by three different types of clinic based on the kind of treatment they offer. Almost all clinics carry out initial fertility assessment, ovulation induction (OI) and intrauterine insemination (IUI). A limited number of clinics can also start and monitor IVF and ICSI treatments, including the ovum retrieval. The laboratory phase of IVF and embryo transfers has to occur in one of the thirteen licensed fertility clinics. Almost all Dutch fertility clinics are funded by the National Health Service. Every Dutch citizen has a basic insurance coverage, which covers treatment and medication costs for OI, IUI and a maximum of three cycles of IVF/ICSI until couples achieve an ongoing pregnancy.

Study population

We performed this study in infertile patients receiving treatment in one of 32 participating Dutch clinics. All patients who participated underwent at least one cycle of medically assisted reproduction (MAR; e.g. OI, IUIs, IVF and ICSI). We only invited the women of the infertile couples to participate in our study as

a previous study has shown that patients' experiences with fertility care are comparable between infertile women and their partners.¹⁴ Patients who were already pregnant at T0 were excluded from follow-up, as our research question did not concern this patient group.

Data collection

T0 measurement

To include a representative patient group for T0 measurement, clinics were asked to extract from their medical records, the address files of all patients who underwent at least one cycle of MAR in their clinic in the previous 3 months (spring–summer 2011). From this list of patients, 25–75 patients per clinic were randomly selected depending on the clinic size. Selected women received a letter in which they were invited to complete an online questionnaire set, accessible by a personal code. Participation was voluntary and anonymous. Patients received a reminder card 2 weeks after the initial mailing. Another 3 weeks later, non-responders received a reminder with the additional option to complete a paper version of the questionnaire.¹⁵

Per clinic, one gynaecologist (i.e. our contact) received an online questionnaire for professionals by e-mail. All 32 gynaecologists received a standard reminder after 2 weeks, and we sent the non-responders an additional reminder 3 weeks later.

T1 measurement

Only the patients who gave consent to follow-up were invited for the T1 measurement (summer 2012). The first steps of questionnaire distribution were performed in the same way as at T0 measurement. Subsequently, an additional reminder was sent to the final non-responders to achieve as high a response rate as possible. The questionnaire at T1 consisted of questions about patients' current status in fertility care. In cases of dropout, we asked for patients' most important reason for discontinuation. To do so, we provided them with a list of 10 different options for dropout, which was based on the literature (e.g. poor response, emotional reasons, ethical reasons or women's age.^{6,7} In case of no valid options, patients had the possibility to add their personal most important reason for discontinuation. Only those patients who discontinued their treatment prematurely were identified as dropouts. However, patients who ended treatment because they have had the maximum of three IVF/ICSI cycles or had no more treatment options were not considered as dropouts. The compliers group consisted of patients who were still under treatment in their own clinic, or patients who had no more treatment options in their own clinic and, therefore, went to another

clinic. Patients who went to another clinic because they were unsatisfied with their clinic were excluded from analysis.

Questionnaires at T0 measurement

Patients' questionnaire

The questionnaire set for patients consisted of several background questions for case-mix adjustment and the PCQ-Infertility questionnaire. The background questions were based on both general and fertility care related issues described in the literature as possibly being linked to dropout and/or patient-centred care^{12,16-19}, including issues related to the quality of life (FertiQoL questionnaire²⁰) and risk factors for emotional maladjustment during treatment (SCREENIVF questionnaire²¹).

The PCQ-Infertility is a validated instrument measuring patient-centredness of fertility care by asking patients about their experiences with care. This questionnaire is composed of 46 questions and contains 7 subscales, namely: accessibility (two items, Cronbach's $\alpha = 0.64$, e.g. 'Was it a problem for you to contact staff if you had any questions?'); information (11 items, Cronbach's $\alpha = 0.73$, e.g. 'Did you receive an overview of your treatment plan with a time schedule?'); communication (seven items, Cronbach's $\alpha = 0.78$, e.g. 'How often did your physician take you seriously?'); respect for patients' values (seven items, Cronbach's $\alpha = 0.85$, e.g. 'How often did your physician show an interest in your personal situation?'); continuity and transition (seven items, Cronbach's $\alpha = 0.66$, e.g. 'How often did you have an appointment with the same physician?'); patient involvement (three items, Cronbach's $\alpha = 0.75$, e.g. 'Was decision-making shared with you, if preferred?') and competence (six items, Cronbach's $\alpha = 0.72$, e.g. 'How often was your physician well-prepared for an appointment?'). A higher score on the total PCQ scale or one of the subscales (range 0–3) indicates a higher level of experienced patient-centredness.¹⁰

Professionals' questionnaire

We used a questionnaire for professionals to gather the remaining clinic characteristics as potential predictors of dropout. The representative gynaecologists of all 32 participating clinics received a short online questionnaire with eight questions about their clinic. The selection of the clinic characteristics was based on the literature as possibly being related to patient-centred care^{12,16,17}, and included the number of gynaecologists, the number of new fertility patients per year, presence of a separate waiting room for infertile patients (yes/no), a separate room for semen production (yes/no), specialized fertility nurse(s) (yes/no), having a psychologist as part of the fertility team (yes/no), structured (e.g.

weekly) meetings to discuss all (new) patients within the team (yes/no) and execution of structured (e.g. yearly) quality measurements before the start of this study (yes/no).

Ethical approval

The institutional ethics committee of Radboud University Nijmegen Medical Centre provided ethical approval for this research to proceed (CMO nr 2011/034). A written informed consent had been obtained at T0 from all participants.

Data analysis

We first performed a power analysis using the model of Tosteson.²² We considered an odds ratio (OR) of 1.5–2.0 for 1 SD increase in exposure as clinically relevant, resulting in a minimum required number of 115 to 317 patients ($\alpha = 0.05$, $\beta = 0.8$).

We categorized all patients into five groups depending on their current status in fertility care and compared all background characteristics between these groups. The five groups included (i) patients who had achieved pregnancy between T0 and T1; (ii) patients who were still under treatment (i.e. compliers); (iii) patients who dropped out of treatment; (iv) patients who ended treatment for medical reasons (e.g. having the maximum of three IVF cycles, or poor prognosis) and (v) patients who were lost to follow-up. We used one-way analysis of variance and chi-square tests to compare these groups on continuous and categorical patient characteristics, respectively.

For further analyses, we used the data of groups 2 (i.e. compliers) and 3 (i.e. dropouts), as our research question concerned these patients only. Patient characteristics that showed significant differences between these two groups were taken up as case-mix adjusters in the final analysis. Subsequently, all clinic characteristics were included in multiple binary logistic regression analyses to evaluate them as a potential predictor of dropout. Compliers and dropouts acted as the dependent variable.

For our additional analysis, we divided our patient group into patients undergoing ART and patients undergoing non-ART at T0. Then, we determined to what extent the treatment type and PCQ-Infertility total scores were related to each other, using linear regression analyses. In case of a significant correlation, we performed our previous analyses on these two groups separately. Significance for all analyses was set at $P < 0.05$. Analyses were performed using the Statistical Package for the Social Sciences (version 18.0 for Windows®, SPSS Inc., Chicago, IL, USA).

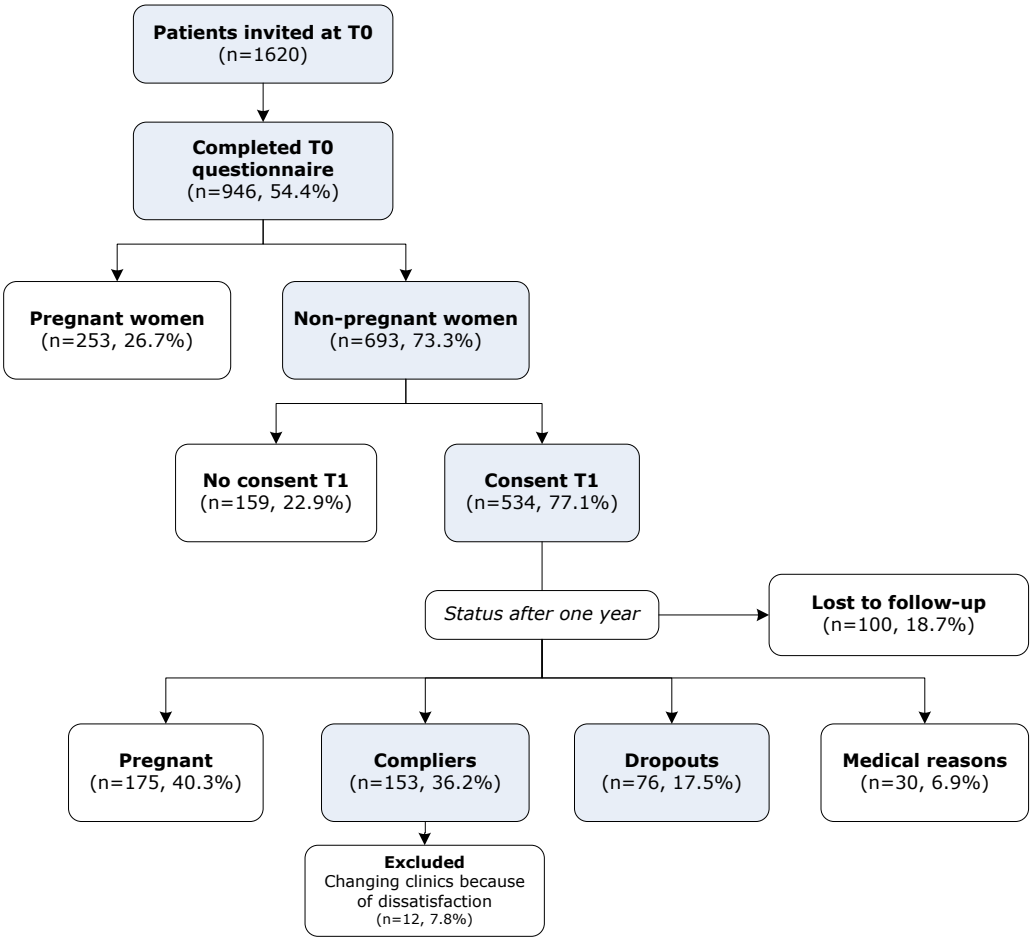
Results

At T0 measurement, 1620 women were invited to participate, of which 946 completed the questionnaire (response rate 58.4%). After excluding 253 pregnant women, 693 women were eligible for participation in the follow-up study. Of this group, 534 women (77.1%) provided consent for the follow-up. At T1 measurement, 434 women completed the questionnaire (response rate 81.3%). Of these women, 175 (40.3%) had achieved pregnancy and 153 women (35.2%) continued treatment since T1 measurement. Of these women, 12 (7.8%) changed clinics because they were unsatisfied with the care they received in their clinic and were, therefore, excluded, leaving 141 patients in the compliers group. Further, a total of 76 women (17.5%) dropped out treatment and 30 women (6.9%) had stopped because of medical reasons. Figure 1 presents the flowchart of this study. From the 76 women, who dropped out, 31 women (40.8%) mentioned emotional problems as their most important reason and 10 patients (13.2%) stated that they had relational problems. Also, female age increased the risk of birth defects ($n = 10$; 13.2%) and fundamental reasons (e.g. considering IVF as a step to far; $n = 5$; 6.6%) were mentioned as reasons for dropping out. In addition, as we included 217 patients in our main analysis, it seems we have no remarkable limitations in sample size considering our previous power calculation.

All patient characteristics are presented in table 1, divided according to their current status in fertility care. Patients who ended treatment because of medical reasons were significantly older and less well educated, had longer experiences in fertility care and had undergone ART more often than patients in the other groups. Furthermore, patients who dropped out of treatment were significantly older than the patients who became pregnant, the compliers or the patients lost to follow-up. Female age was, therefore, taken up as a case-mix adjuster.

Table 2 presents the results from the PCQ-Infertility, including all median PCQ-Infertility total and subscale scores. Logistic regression analyses with adjustment for age showed that women's PCQ-Infertility total and subscale scores do not differ significantly between dropouts and compliers. Additional analyses on the subgroup of patients who went to another clinic because they were unsatisfied ($n = 12$) did not show any differences with the compliers group on the PCQ-Infertility total and subscales (data not shown). Table 3 shows the results from the additional clinic characteristics, which also do not differ between dropouts and compliers.

Figure 1
Flowchart of the longitudinal study of patient-centredness to identify factors, which predict dropout in fertility care



The results from the analyses of the non-ART and ART subgroups are presented in table 4. It was appropriate to perform these analyses as the PCQ-Infertility total scores were significantly related to the treatment type [$\beta = -0.231$; 95% confidence interval (CI) = -0.302 to -0.160; $P = <0.001$]. In the non-ART subgroup, a lower score on the PCQ subscale 'Respect for patients' values' was significantly related to higher dropout (OR 0.57; 95% CI 0.34–0.95). In the ART subgroup, a higher score on the PCQ subscale 'Patient Involvement' was associated with higher dropout (OR 2.39; 95% CI 1.02–5.59). We found no significant differences within both subgroups for the additional clinic characteristics.

Table 1
Background characteristics of the cohort (*n* = 534) in a longitudinal study to identify factors, which predict dropout in fertility care

Patient characteristics	1. Pregnant (<i>n</i> =175)	2. Completers (<i>n</i> =141)	3. Dropout (<i>n</i> =76)	4. Medical reasons (<i>n</i> =30)	5. Lost to follow-up (<i>n</i> =100)	P-value
Median age Years (<i>range</i>)	32 (21-42)	32 (23-42)	34 (24-44)	37 (26-42)	32.0 (22-44)	<0.01 ^a
Ethnic background (%) Dutch / Western / non-Western	91.4 / 2.9 / 5.7	87.2 / 5.0 / 7.8	90.8 / 5.3 / 3.9	93.3 / 3.3 / 3.3	88.3 / 1.9 / 9.7	0.57
Level of education (%) Low - medium / High	53.4 / 46.6	44.7 / 55.3	48.7/51.3	73.3/26.7	53.4/46.6	0.04 ^b
Duration of infertility Months (<i>range</i>)	29 (3-133)	34 (1-103)	34 (4-142)	40 (2-104)	35 (5-121)	0.19
Duration of fertility care experience Months (<i>range</i>)	14 (1-109)*	17 (1-86)	21 (1-127)	30 (4-89)	19.0 (1-118)	0.02 ^c
Diagnosis (%) Male factor / Female factor / Both / Unexplained	20.7/34.1/13.4/31.7	20.5/29.5/8.2/41.8	17.9/38.4/13.4/40.3	37.0/22.2/11.1/29.6	20.2/31.6/11.0/36.8	0.56
Treatment type (%) ART / non-ART	42.9 / 57.1	45.6 / 54.4	45.3 / 54.7	93.3 / 6.7	46.0 / 54.0	<0.01 ^b
Professional emotional support (%)	10.4	12.1	11.8	10.3	14.0	0.90
Lifetime events (%)	11.5	14.9	7.9	10.0	4.9	0.08
FertiQoL (0-100, <i>range</i>)	69.8 (32.3-95.2)	70.8 (27.1-92.7)	70.8 (37.5-90.6)	72.9 (35.4-91.7)	66.7 (31.3-96.8)	0.44
SCREENIVF (%)	63.2	65.9	60.6	69.2	65.6	0.81

One-way analysis of variance and Chi-square tests were used for continuous and categorical variables, respectively.

^a Both the 'dropout' and the 'medical reasons' groups differ significantly (*P* < 0.05) from the other groups.

^b The 'medical reasons' group differs significantly (*P* < 0.05) from the other groups.

^c Both the 'pregnant' and the 'medical reasons' groups differ significantly (*P* < 0.05) from the other groups.

Table 2
The relation between the level of patient-centredness and dropout

	Compliers (n=141)		Dropout (n=76)		Compliers versus dropout	
	Median	(range)	Median	(range)	OR	95% CI
PCQ-Infertility (0-3)	2.24	(1.04-2.93)	2.18	(0.67-2.95)	0.73	(0.37 – 1.46)
Accessibility of care	2.50	(0.00-3.00)	2.50	(0.50-3.00)	1.07	(0.71 – 1.61)
Information provision	2.09	(0.60-3.00)	2.00	(0.00-3.00)	0.79	(0.49 – 1.30)
Communication	2.57	(0.57-3.00)	2.57	(0.14-3.00)	0.82	(0.47 – 1.43)
Respect for patients’ values	2.00	(0.14-3.00)	1.80	(0.00-3.00)	0.72	(0.49 – 1.05)
Continuity and transition	1.86	(0.67-3.00)	1.79	(0.43-3.00)	0.87	(0.52 – 1.46)
Patient involvement	2.33	(0.00-3.00)	2.67	(0.33-3.00)	1.24	(0.78 – 1.97)
Staff’s competence	2.50	(1.17-3.00)	2.50	(0.67-3.00)	0.80	(0.40 – 1.62)

Data presented as OR’s and 95% CI. Binomial logistic regression analysis was used to compare patients under treatment with patients who dropped out treatment. The results are adjusted for age.

Table 3
The relation between additional clinic characteristics and dropouts

Clinic characteristics	Compliers (n=141)		Dropout (n=76)		Compliers vs. dropout	
					OR	(95% CI)
Number of patients per clinic <i>Median (range)</i>	444	(110–2600)	500	(110–2600)	1.00	(1.00 – 1.01)
Separate waiting room for infertile patients <i>Number (%)</i>	55	(39.0)	23	(30.3)	0.65	(0.35 – 1.19)
Specialized fertility nurses <i>Number (%)</i>	96	(68.1)	57	(75.0)	1.57	(0.82 – 3.02)
Regularly measuring clinic’s quality levels <i>Number (%)</i>	77	(54.6)	39	(51.3)	0.88	(0.50 – 1.56)
Structured meetings to discuss all patients <i>Number (%)</i>	116	(82.3)	67	(88.2)	1.80	(0.78 – 4.18)
Number of gynaecologists <i>Median (range)</i>	3	(1–7)	2	(1 –7)	0.81	(0.67 – 1.00)
Separate semen production room <i>Number (%)</i>	89	(63.1)	47	(61.8)	1.11	(0.61 – 2.02)
Presence of clinic psychologist(s) <i>Number (%)</i>	116	(82.3)	62	(81.8)	0.96	(0.46 – 2.03)

Data presented as OR’s and 95% CI. Binomial logistic regression analysis was used to compare patients under treatment with patients who dropped out treatment. The results are adjusted for age.

Table 4**Clinic characteristics and dropouts; differences between patients who received ART and non-ART**

Clinic characteristics	Compliers vs. dropout		Clinic characteristics	Compliers vs. dropout	
	ART (n=96)	Non-ART (n=115)		ART (n=96)	Non-ART (n=115)
	OR (95% CI)	OR (95% CI)		OR (95% CI)	OR (95% CI)
PCQ-Infertility (0-3)	1.51 (0.48-4.79)	0.52 (0.20-1.38)	Number of patients per clinic	1.00 (0.99-1.00)	1.00 (0.99-1.00)
Accessibility of care	0.91 (0.50-1.67)	1.27 (0.71-2.26)	Separate waiting room for infertile patients	0.75 (0.31-1.82)	0.57 (0.23-1.41)
Information provision	1.32 (0.53-3.26)	0.59 (0.28-1.25)	Specialized fertility nurses	1.93 (0.53-7.07)	1.66 (0.73-3.76)
Communication	1.25 (0.46-3.38)	0.77 (0.38-1.56)	Regularly measuring clinic's quality levels	1.08 (0.43-2.68)	0.70 (0.31-1.56)
Respect for patients' values	1.17 (0.60-2.27)	0.57 (0.34-0.95)*	Structured meetings to discuss all patients	2.45 (0.46-13.00)	1.64 (0.59-4.55)
Continuity and transition	0.89 (0.40-1.98)	0.96 (0.48-1.95)	Number of gynaecologists	0.71 (0.47-1.10)	0.85 (0.67-1.08)
Patient involvement	2.39 (1.02-5.59)*	0.99 (0.55-1.77)	Separate semen production room	1.50 (0.54-4.18)	1.10 (0.49-2.45)
Staff's competence	1.83 (0.56-5.93)	0.52 (0.20-1.32)	Presence of clinic psychologist(s)	1.21 (0.35-4.12)	0.89 (0.34-2.30)

Data presented as OR's and 95% CI. Binomial logistic regression analysis was used to compare patients under treatment with patients who dropped out treatment for both the ART treatment and non-ART treatment groups. The results are adjusted for age.

Discussion

This study shows that patients' experiences with patient-centred fertility care are not related to dropout, as the PCQ-Infertility scores did not differ between patients who continue and patients who discontinue their fertility treatment. Also the additional clinic characteristics were not related to dropout. However, when focusing on subgroups of patients, the PCQ-Infertility subscale 'Respect for patients' values' negatively predicted dropout in patients receiving non-ART. Moreover, the subscale 'Patient involvement' was a positive predictor of dropout in patients undergoing ART treatments. These are important findings as clinic factors have rarely been studied as potential predictors of dropout. Therefore, the results of this study provide more insights into fertility clinics' characteristics that do and do not predict dropout and the direction (i.e. positive or negative) in which this prediction might be.

It is remarkable that the level of patient-centredness that patients assign to their clinic was not related to dropout, since both qualitative and quantitative studies showed that infertile patients consider their clinic's level of patient-centredness

very important.^{11,12,23} A study of van Empel *et al.* also demonstrated that patients were willing to trade of up to a third of their pregnancy rate for more patient-centred care.¹¹ Moreover, a lack of patient-centredness was found as the most common reason for patients to change clinics.^{11,24} These findings notwithstanding, we can now conclude that, in our study setting, patients' experiences with patient-centred care seem to be no optimal predictor of dropout. Still, it might be too restrictive to state that clinic factor could never be used as a predictor of dropout. Our study was performed within one European country, while it is known that the quality of care varies according to cultural and social settings.²⁵⁻²⁷ Extending our study to a more international setting might, therefore, influence the results. Moreover, dropout in relation to patient-centred care could be more relevant for specific treatment types⁷, as we have shown in our study. First, patients who received non-ART had more chance of dropping out when they scored lower on the 'respect for patients' values' subscale (i.e. a negative predictor). It is already known from the literature that non-ART patients are generally more dissatisfied with their care than patients receiving ART.^{10,16,17} This can be better understood, knowing that non-ART procedures are generally performed in less specialized fertility clinics, by more general gynaecologists compared with the more specialized gynaecologists and nurses in fertility centres. Our study showed that especially patients undergoing non-ART are sensitive to the respect they receive from the professional team. As a result, paying less attention to patients' values led to more dropouts, which can be considered a negative effect in fertility care. Therefore, professionals treating non-ART patients should give these patients the personal attention they need and respect them in their values and needs.

The second possible predictor of dropout in our additional analyses was 'Patient involvement'. Patients receiving ART were more likely to dropout when the level of patient involvement was higher (i.e. a positive predictor). Patients do not always know that they also have the option to withdraw from treatment. Achieving awareness of this and involving patients in the decision process could make this clear to them.²⁸ Apparently, patients' decision to discontinue treatment is taken more easily when they are well informed and involved in all treatment phases, as we have shown in our study. Other studies in fertility care illustrate this as well. For example, van Peperstraten *et al.* found that empowering infertile patients by giving them a decision aid made them choose to replace fewer embryos in IVF.²⁹ Also, studies from other health care areas have shown the relation between patient empowerment and a reduction in care consuming.^{30,31} From this point of view, dropping out or discontinuing treatment might be considered a positive choice in fertility care as it is well informed and without decisional conflict.

This line of thought could shed light on the complex issue of dropout. Dropping out of treatment could be a positive, well-informed choice. This decisional process

seems to be supported by involving patients in their care and by respecting their values regarding treatment options. On the other hand, a negative choice to dropout could be explained by an inability to continue because of emotional or other personal reasons. This is supported by studies indicating stress or emotional strain as reasons for dropout. In previous research, dropout is mainly considered as a negative decision as patients were unsatisfied with the organization of care or mentioned poor communicating skills of the staff as their reason for discontinuation.^{1,9} The results of our study might indicate that patients' decision to dropout of fertility care is more heterogeneous, as their decision was related to negative evaluations of patient-centred care (i.e. less respect of patients' values), but also to positive evaluations (i.e. more patient involvement). We might, therefore, speak about dropouts as following a positive or after a negative choice.³² To underline or reject this hypothesis, more research is obviously needed, for example, regarding the process underlying the decisions that infertile patients make. The results of our study could be helpful in the initiation of future research about this topic.

This study has several strengths. First, we included more than 500 infertile women from all areas across the Netherlands, ensuring representativeness of the Dutch infertile population. Second, we included patients in different treatment phases, while previous studies mainly focused on patients undergoing IVF and/or ICSI treatments. By including such a varied group of patients, we were able to evaluate predictors of dropout in almost the entire setting of fertility care. Moreover, we performed additional analyses, enabling us to draw conclusions on the different treatment phases as well. Third, we explored all different elements of 'clinic factors' by including both 'standard clinic characteristics' (e.g. clinic size) and clinic factors evaluated by the patients themselves. By including the PCQ-Infertility questionnaire, we were able to evaluate clinics from the perspective of the patients. Finally, we compared various patient characteristics between the dropouts and compliers, including patients' quality of life, and corrected them if necessary. We also added the non-responders to this comparison, showing that their background characteristics did not differ significantly from the patients we included in the analysis.

Some limitations of this study should also be discussed. First, we were not able to follow-up all 534 patients who provided consent for this study at T0, which might have biased our results. However, due to the effort of sending additional reminders, we managed to reach a response rate of >80% at the T1 measurement. It should, however, be noticed that the response rate of T0 was 58.4% and, subsequently, we lost 22.9% of patients between T0 and T1, because they were not willing to participate in our prospective study. Bias of our results is, therefore, more likely and should be taken into account when interpreting our results.

Second, we only included patients who already started treatment for their fertility problem and, consequently, left out those patients who dropped out during or even before diagnostic fertility work-up. Brandes *et al.* showed that already at this stage, patients drop out.⁶ However, the PCQ-Infertility was not validated for this group of patients, as they have not visited their clinic often enough to evaluate it appropriately. Consequently, we decided not to include these patients in our study. Third, we used a definition for dropout that might be somewhat different from the definition used in several other studies. Generally, dropout is defined as every premature discontinuation of treatment in that particular clinic. As we included patients from different clinics across the Netherlands and from all different treatment types, our study setting was somewhat different. Consequently, patients also ended treatment in their clinic, because they needed a treatment in another clinic or simply had no more treatment options. Because of this specific situation, we decided to exclude these patients from the dropout group. Following the literature, these patients can be considered as 'active censored' or 'physician-recommended dropouts'. Consequently, we included patients who were 'passive censored' or 'patient-initiated dropouts'.^{33,34} We also excluded patients who went to another clinic because they were unsatisfied with their current clinic, as they did not fit our definitions of 'dropouts' or 'compliers'. However, we considered this an interesting subgroup of patient and performed additional analyses on this group. We found no relation to dropout, but this could very well be due to the small sample size ($n = 12$).

The results of our study led to some recommendations for daily practice and future research. The fact that we did not find any association between clinic factors and dropouts in our entire patient group could imply that this association does not exist at all. If this is true, dropouts might be more related to factors at the patient and the treatment level and further research should concentrate on these elements. Another explanation for the lack of relationship between patient-centredness and dropout is the heterogeneity of the sample regarding the centre, phase of treatment and treatment type. Despite the fact that we controlled for clinical characteristics and that we performed separate analyses for patients undergoing ART and non-ART, the patients relate their scores on patient-centredness to their experience with their own clinic, which could explain the lack of significant relationships. In addition, dropout might be explained by a complex interplay of clinical, personal and treatment-related factors.⁸ It is possible that clinical factors play a role in patients who experience a lot of distress. This means that the results of this study do not justify the exclusion of clinical factors as possible contributors to dropout. More in-depth analyses are warranted to control for clinical differences, which will require large samples. Obviously, predicting dropout in fertility care is complicated given the number of

studies on this subject and their conflicting outcomes.^{4,35-40} We have made a first initiative to show the relation between clinic factors and dropouts in a prospective setting. Future research should concentrate on more different patient, treatment and clinic factors and their possible interactions in order to identify appropriate predictors of dropout in fertility care.

In conclusion, patients' experiences with patient-centred fertility care are not related to dropout. However, within two subgroups of patients (i.e. receiving non-ART and ART), we have collected some clues that clinic factors could be used as a predictor of dropout in specific patient groups. In future research, it would be interesting to find more predictors of dropout at the patient, treatment and clinic levels and explore their possible interactions. Only then, will we gain an optimal insight into those factors influencing dropout, making it possible to account for them in daily clinical practice.

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"WE WILL GET YOU PREGNANT, LADY!" THESE WERE LITERALLY THE WORDS OF THE DOCTOR WHO WOULD MAKE SURE THAT I GOT WHAT I WANTED: A BABY. OF COURSE, I KNEW THAT THE CHANCE TO ACHIEVE PREGNANCY WAS FAR FROM GUARANTEED, BUT IT USED TO SOUND LIKE: "PLEASE, DO NOT THINK TOO MUCH ABOUT IT. YOUR GYNÁECOLOGY WILL MAKE SURE THAT IT WILL ALL TURN OUT WELL IN THE END." NO, THIS WAS DEFINITELY NOT WHAT I EXPECTED FROM A PATIENT-CENTRED CARE? I CAN ANSWER THIS QUESTION WITH A CATEGORICAL NO. MY HUSBAND AND I EXPERIENCED DURING THE FIVE YEARS THAT WE WERE WAITING FOR A CHILD DURING THESE YEARS, WE WENT THROUGH DIFFERENT POSITIVE AND NEGATIVE EXPERIENCES. TO MAKE IT MORE UNDERSTANDABLE HOW IT IS TO BE A PATIENT WITH INFERTILITY, I WILL SHARE SOME OF MY EXPERIENCES. AFTER I HAD UNDERGONE A LAPAROSCOPY TO FIGURE OUT WHY I WASN'T GETTING PREGNANT, A NEW APPOINTMENT WITHIN TWO WEEKS TO START UP A NEW TREATMENT WAS SURPRISINGLY ANSWERED: 'THIS MUST BE A MISTAKE, BECAUSE IT'S TOO EARLY AFTER SURGERY. OBVIOUSLY, YOUR BODY NEEDS MORE TIME TO RECOVER.' THAT WAS REALLY WHAT THE DOCTOR HAD TOLD ME. BUT BEFORE I COULD RETURN TO MY COLLEAGUE. AGAIN, SHE ONLY CONFIRMED WHAT HER COLLEAGUE HAD SAID. MY RETURN WITHIN TWO WEEKS TO CONTINUE MY TREATMENT (AND I HAD TO WAIT FOR THE SECRETARIES, WHO WERE ALSO FIRM IN THEIR STATEMENTS. I COULD NOT GO. THERE WAS NO PROBLEM TO SEE THE DOCTOR AND THERE WAS NOTHING WRONG WITH ME. I WAS VERY INSECURE AND HAD STRESSED ME OUT, WHICH OBVIOUSLY OFTEN HAD TO SIT NEXT TO PATIENTS WHO WERE ALREADY PREGNANT AND WERE TALKING ABOUT THE PROGRESS OF THEIR PREGNANCIES TOGETHER. THAT'S GOOD FOR INFERTILITY. IT WAS VERY HARD FOR ME TO SEE ALL THESE BIG BELLYS. THE DOCTOR ASKED ME TO RETURN TO THE WAITING ROOM FOR A FEW MORE MONTHS. THERE I WAS, SITTING NEXT TO A MOTHER WITH A TWO-YEAR OLD CHILD. SHE WANTED TO PUT MYSELF IN HER SHOES AND FELT REALLY MISERABLE. MY OWN EXPERIENCE WAS NOT REALLY IMPRESSIVE. FOR EXAMPLE, IT HAPPENED SEVERAL TIMES THAT I DID NOT GET AN APPOINTMENT. OBVIOUSLY, THE DOCTOR WAS NOT AWARE OF THE FACT THAT I HAD TO READ MY MEDICAL RECORD BEFORE I ENTERED THE ROOM. ALSO, THE INFORMATION WAS CONTRADICTORY. IT SEEMED LIKE ALL DOCTORS HANDLED OUR CASE DIFFERENTLY. IT SCARED ME A LITTLE BIT, AS I ALREADY FELT PSYCHOLOGICAL PRESSURE. THAT MY DOCTORS WERE ALL POINTING IN THE SAME DIRECTION. I FELT THAT OUR OWN DOCTOR SHOULD NEVER HAVE INTRODUCED THE IVF TREATMENT OPTIONS. VERY CONFUSING, AS WE DID NOT KNOW WHAT THE BEST NEW TREATMENT I READ ABOUT IN A MAGAZINE. OUR DOCTOR HAD SAID THE OPPOSITE WAS TRUE ACCORDING TO THE LATEST RESEARCH. ELIGIBLE FOR THIS TREATMENT BEFORE. EVENTUALLY, I WAS TOLD THAT I WAS NOT ELIGIBLE. EVA W. VERKERK
BLIND DATE. POOR COMMUNICATION, MY HUSBAND AND I WERE NOT TALKING ABOUT IT. ULTRASOUND CHECK-UP, A LOT OF SMALL FOLLICLES WERE VISIBLE. THAT'S WHY I HAD AN APPOINTMENT TO ME, BUT MY DOCTOR JUST SAID: 'YOUR OVARY LOOKS FINE, BUT THIS IS NOT WHAT YOU NEED OF COURSE!' WELL, THAT'S NOT WHAT I WOULD LIKE TO SHARE, IS ABOUT MY ADMIS- EDDY M.M. ADANG
LOSS DURING MY PREGNANCY. YES, WE FINALLY GOT PREGNANT AFTER SEVERAL YEARS. JOHN APPLEBY
AN UNEXPECTED LOSS. THEREFORE, IT WAS EVEN MORE STRIKING WHEN THE DOCTOR ENTERED MY ROOM: 'IT IS VERY NICE AND QUIET ON THIS SECTION. I HEARD YOU HAD A LOSS. HE ASKED ME HOW I WAS DOING. I TOLD HIM I WAS 'ALLOWED' TO GO HOME, HE SAID. HE OBVIOUSLY THOUGHT THAT I WASN'T. OF JAN A.M. KREMER
I WOULD HAVE PREFERRED TO STAY ANOTHER DAY. A PERFECT EXAMPLE OF 'TALKING ABOUT THE PATIENT', INSTEAD OF

CHAPTER 6

THE MONETARY VALUE OF PATIENT-CENTRED CARE:

RESULTS FROM A DISCRETE CHOICE EXPERIMENT IN

DUTCH FERTILITY CARE

SUBMITTED

Abstract

Background

The benefit patients derive from treatment arise from a number of aspects of their care, such as their safety, medical outcome, but also patient-centred factors. Understanding the values patients place on these care dimensions is important if professionals are to improve the overall benefits they provide for their patients and if health insurers are to contract with those clinics that best meet the needs of their members. This study assesses the value patients and insurers place on different aspects of treatment in the area of fertility care, with a particular focus on patient-centredness.

Methods

A discrete choice experiment (DCE) was constructed to assess both patients' and health insurers' hypothetical choices of fertility clinics based on clinics' performance on: the pregnancy rate, patient-centredness levels (i.e. information provision, patient involvement, and continuity of care) and additional costs per treatment cycle. 996 patients and 84 healthcare insurers received the DCE-questionnaire. With logistic regression analysis, we calculated the willingness-to-pay values for more effective and patient-centred fertility care.

Results

550 patients (55.4%) and 45 healthcare insurers (53.6%) completed the DCE questionnaire. Patients were willing to pay a medium amount of €463 for a relevant one-step increase in patient-centred care and €107 for one percent increase in pregnancy rates. Healthcare insurers' valuations were lower: €191 for more patient-centred care and €60 for one percent increase pregnancy rates. The willingness-to-pay values depended on patients' age, patients' ethnicity, income, and treatment type and on health insurers' age.

Conclusions

This study emphasises the importance of patient-centredness for both patients and their insurers. Therefore, efforts by policymakers and clinicians to improve these aspects of care would increase the overall value patients derive from their treatment. Although insurers placed a lower monetary value on patient-centredness aspects than patients, insurers' purchasing decisions should be guided by patient rather than insurer preferences.

Background

Providing patient-centred care has become an important and central aim in current healthcare.¹ This is reflected in the numerous studies exploring the concept of 'patient-centredness' in recent years.²⁻⁵ In general, patient-centredness is defined by respectfulness of and responsiveness to patients' preferences, values and needs.² Moreover, it is recognized as a multidimensional concept^{2,3,5}, including domains on the organizational and the human level.⁶ For example, patients want shorter waiting times and optimal continuation of care, but patients also want to trust their doctor by receiving clear and customized information, they want to be treated as a person, and be involved in decision making.^{7,8}

So far, it seems like the content of 'patient-centredness' is diverse, but clearly studied. However, its integration in daily care is more complicated as the benefits patients derive from treatment arise from several aspects of care, including not only patient-centred factors but also for example their safety and medical outcome. If professionals want to improve the overall benefits they provide for their patients, including the patient-centred aspects of care, they should understand the values patients place on the different dimensions of care first. This information would also guide policy makers to assign public resources to care elements most relevant to the healthcare consumer.⁹ Furthermore, it could stimulate health insurers to contract with those clinics that best meet the needs of their members. An increasingly popular method to determine the relative importance of outcome measures is by assigning it a monetary value.¹⁰

Therefore, the main aim of this study is to estimate the monetary value both patients and health insurers place on different aspects of healthcare, with a particular focus on the patient-centredness of care. We performed our study in the area of fertility care, as it is known that infertile patients suffer from a high physical and psychological burden during treatment and could therefore especially benefit from patient-centred care.¹¹ Moreover, the concept of patient-centred fertility care is explored extensively and leaves room for improvement.^{6,12,13}

Methods

Study design

We used a discrete choice experiment (DCE) design, to estimate the monetary value both patients and health insurers place on different aspects of fertility care. We examined the relative weight patients and health insurers place on relevant aspects of fertility care with respect to costs through a questionnaire with choice sets representing hypothetical but realistic fertility clinics. We asked

patients which fertility clinic they would choose for their treatment and health insurers which clinic they would prefer to purchase healthcare for their insurance company. The institutional ethics committee of Radboud University Nijmegen Medical Centre provided ethical approval for this research to proceed (CMO nr 2011/034). Our study was registered with ClinicalTrials.gov (NCT01834313) and we reported our results according to the STROBE statement for observational studies.

Setting and study population

Due to the unique Dutch health system, which is based on managed competition¹⁴, we included both a group of infertile patients and a group of Dutch health insurers. Dutch health insurers can be considered as the patients' representatives in healthcare as they are the prudent purchasers of care for their customers (i.e. patients). Health insurers negotiate with care suppliers about the quality and costs of care and have the freedom to selectively contract care suppliers based on adherence to quality standards and price levels. Furthermore, Dutch citizens are forced to purchase a basic insurance package from a health insurer of their choice and have the option to purchase supplementary insurance for additional healthcare.¹⁴ Concerning fertility care, the basic insurance package covers treatment and medication costs for ovulation induction (OI), intra-uterine inseminations (IUI), and three cycles of IVF/ICSI per episode. Supplementary insurance could cover the costs for the fourth or fifth IVF/ICSI cycle or annual subscription costs for the Dutch Patients' Association of Infertility.

We selected patients from ten Dutch fertility clinics throughout the country, consisting of four large IVF centres and six medium-sized clinics. The IVF centres are licensed to perform all phases of all different fertility treatments, while the medium-sized clinics refer their patients to a larger centre for the laboratory phase and embryo transfer of the *In Vitro* Fertilization (IVF) and Intra-cytoplasmic Sperm Injection (ICSI) treatments. To include a representative patient group, clinics were asked to extract the address files of all patients who underwent at least one cycle of a fertility treatment in their clinics in the past three months (summer 2012) from their national coding system for diagnosis and treatment. We randomly selected 50 couples per clinic, of whom the women and their partners were invited to participate individually. Finally, we asked all Dutch health insurers responsible for purchasing healthcare (n=84) from the five largest Dutch health insurer companies to participate in our study.

Development of the DCE-questionnaire

The first step in questionnaire development was the selection of care elements

most relevant for patients and health insurers in a fertility care setting. We based this selection on the existing literature about patients' preferences in fertility care^{13,15-17} and an interview with the Chief of the 'Healthcare purchasing department' of one of the largest Dutch health insurer companies. We discussed it within an expert panel of clinicians and methodologists and determined both the effectiveness and patient-centredness as pivotal factors for decision making in fertility care.^{6,12,15} The panel selected the four most relevant attributes covering these two care aspects and divided each attribute into three levels covering a 'realistic range' (Table 1). The levels of 'ongoing pregnancy rate' (i.e. effectiveness of fertility care) ranged from 20% to 35%, corresponding the actual mean ongoing pregnancy rates in Dutch fertility clinics.¹⁸ Three attributes were selected to represent patient-centredness (i.e. information provision, patient involvement and continuity of physicians), which was based on previous studies about patient-centred fertility care in the Netherlands.^{12,13} We performed a pilot study among 13 patients and a health insurer to determine the levels of the fifth attribute 'additional costs per IVF cycle'. For both parties a range from zero to €500 seemed suitable.

The combination of five attributes, each consisting of three levels, resulted in 243 (3⁵) hypothetical scenarios for fertility care. To create a more functional sample, we used a fractional factorial design which was based on an 81 array orthogonal main effects plan.¹⁹ This guarantees an optimal balance of attributes and levels with a minimal correlation.²⁰ Subsequently, we created choice sets existing of two scenarios by means of a fold over technique (22222), ensuring maximum differentiation between attribute levels within each scenario.²¹ As a result, 162 (2 * 81) of the 243 possible scenarios were included. The efficiency of this design was considered most optimally (i.e. 100%).¹⁹

Clearly, a respondent would not be able to complete all 81 choice sets, although studies have shown that the amount of choice sets only slightly influences the error of variance^{20,22} For this study, we created five different questionnaire versions for the patients: four with 16 choice sets and one with 17 choice sets. For healthcare purchasers, we composed four different questionnaires (four questionnaires with 20 choice sets and one with 21 choice sets). All questionnaire versions were tested for level balance and consisted of two dominant choices to assess the understanding of the attributes by the participants. These choices were characterized by logically preferable levels on all attributes. Respondents who "failed" at both tests were defined as "irrational" and dropped from the analyses.²¹ Finally, all questionnaires consisted of additional background questions to account for heterogeneity of our study population, such as gender, age, ethnicity, education and income.

Table 1
Attributes and corresponding levels

Attributes	Levels
Clinic’s mean ongoing pregnancy rate	20% 30% 35%
Information provision	Contradictory information Only general information Clear and customized information
Patient involvement	Never Sometimes Always
Continuity of physicians	Seeing a different physician almost every visit Having one lead physician Always seeing your own physician
Additional costs per IVF cycle	€0,- €200,- €500,-

Data collection

The questionnaires were randomly divided over a total of 993 patients (497 women and 496 partners) and 84 Dutch healthcare purchasers. Participation was voluntary and anonymous. All participants received a reminder card two weeks after the initial mailing. Another three weeks later, non-responders received a second reminder.

Data analyses

Participants’ preferences regarding fertility care were analysed using generalized estimating equations, an optimal method in cases of correlated responses (i.e. multiple choices per individual).²³ Within this model, we performed binary logistic regression analysis to calculate coefficients for all five attributes, representing the change in benefit for a one-unit change in the attribute level.^{20,21} This was defined by a one percent higher pregnancy rate, one hundred Euros higher costs per IVF cycle, and one level up for the attributes concerning patient-centredness (e.g. from contradictory information to general information). We included interaction terms to account for heterogeneity between subgroups of respondents by using all collected background characteristics. We excluded the statistically insignificant variables via manual backward elimination to come to our final model.

The willingness-to-pay for more effective fertility care was calculated by the ratio of the coefficients 'pregnancy rates' and 'additional costs' for both patients and health insurers. To calculate the willingness-to-pay for more patient-centred care, we aggregated the attribute coefficients of 'Information provision', 'Patient involvement' and 'Continuity of care' to one score. We categorized the sum of the coefficients of the 27 (3^3) possible combinations into three equally large improvement steps (i.e. step 1: from 0 to 9, step 2: from 9 to 18, and step 3: from 18 to 27). For example, step 1 means the improvement from no aspects of patient-centred care to the provision of some aspects of patient-centred care. We calculated the willingness-to-pay of all three improvement steps for both patients and health insurers separately. However, we considered the second improvement step (i.e. from some aspects to several aspects of patient-centred care) as most relevant for clinical practice.^{6,12} Significance for multivariate analyses was set at $P < 0.05$. Analyses were performed using SPSS (version 20.0 for Windows®, SPSS Inc., Chicago, IL, USA).

Results

In total, 282 women (response rate 56.7%) and 268 partners (response rate 54.0%) completed the questionnaire. The healthcare purchasers returned a total of 45 questionnaires (response rate 53.6%). None of the participants failed at the rationality tests. The background characteristics of the patients and healthcare purchasers are presented in table 2.

Table 3 shows the results from the logistic regression analysis. All five attributes had a significant impact on both patients' and health insurers' choice for a fertility clinic, i.e. all attributes were important to them. Almost all coefficients had a positive sign, indicating that participants prefer a clinic with higher level on these attributes (e.g. higher pregnancy rates, or more continuity of care). The negative signs on the cost attribute indicate that both patients and health insurers were less likely to choose a clinic, when costs were higher. Our final model included five interaction terms that were significantly related to patients' or health insurers' choices for a fertility clinic (Table 3, last rows). The costs attribute turned out to be less important for couples with a female age > 36 years, patients with a Dutch ethnicity, a high family income and patients receiving ART treatments. For health insurers, costs were less important for those who were older.

The coefficients of the attributes and interaction terms were used to determine what patients and health insurers were willing to pay for higher pregnancy rates and more patient-centred care, with a special focus on the second improvement step. These results are presented in table 4, showing that patients were willing to

pay a median amount of €107 (range €36 - €187) for 1% higher pregnancy rates and €463 (range €157-€810) for the second improvement step of patient-centred care. Table 4 also shows that patients' willingness-to-pay highly depended on their background characteristics. For example, patients with a low income were willing to pay €59 (€36-€77) for a one percent higher pregnancy rates, while the willingness-to-pay for patients with a high income was €107 (€47-€187). To provide an even more realistic picture of patients' relative valuations of care aspects, we calculated the willingness-to-pay for two specific patients profiles, including all four relevant background characteristics. For instance, a patient older than 36 years with a Dutch ethnicity, a high income, receiving ART treatments was willing to pay €187 for one percent higher pregnancy rates and €810 for the second patient-centredness improvement step.

For health insurers, the median willingness-to-pay for a one percent higher pregnancy rate was €60 (range €27 to €150). For more patient-centred care, health insurers were willing to pay a median expense of €191 (€87-€477) for the second improvement step. The cost attribute appeared to be more important for health insurers who were younger. For example, health insurers being 30 years old were willing to pay a median expense of €101 for more patient-centred care, while health insurers being 50 years old were willing-to-pay €274 for the corresponding improvement step of patient-centred fertility care.

Discussion

Our study showed that the level of patient-centred care significantly influenced patients' choice for a fertility clinic. This is an important finding as it illustrates that consumers in healthcare place a high value on patient-centredness, also in relation to the effectiveness of care. Our results should therefore be stimulating for healthcare providers and policy makers to focus even more on the integration and improvement of patient-centredness in daily clinical care. Moreover, we showed that patient-centredness of care is important to health insurers as well, although to a lesser extent. It is of importance to take their views towards effective and patient-centred care into account, as health insurers can be considered the patients' representatives in the Dutch healthcare system. The results of this study are therefore of interest for many different stakeholders, e.g. patients, health insurers, healthcare professionals, and policy makers and the practical implications should be discussed.

A key strength of our study is the methodologically strong DCE design in which the attributes and levels were optimally balanced. Moreover, we included rationality tests and corrected for several background characteristics to account

Table 2
Baseline characteristics of patients and health insurers

Characteristics	Patients (n = 540)	Health insurers (n = 45)
Age <i>Years (range)</i>	35 (21-53)	41 (25-59)
Gender <i>Male / Female (%)</i>	52.9 / 47.1	61.6 / 38.4
Ethnic background <i>Dutch / non-Dutch (%)</i>	86.3 / 13.7	73.4 / 26.6
Level of education ^a <i>Low – Middle / High (%)</i>	51.2 / 48.8	n.a.
Net monthly family income ^b <i>At or below modal income / $\geq 1.5 \times$ modal income</i>	21.5 / 78.5	n.a.
Median duration of infertility <i>Months (range)</i>	28 (2 -169)	n.a.
Treatment type <i>ART^c / non-ART^d (%)</i>	67.7 / 32.3	n.a.
Being childless <i>Yes / No (%)</i>	67.6 / 33.4	n.a.
Current status <i>Pregnant / non-Pregnant (%)</i>	22.7 / 77.3	n.a.
Experience as health-care purchaser <i>Years (range)</i>	n.a.	5 (1-37)
Considering infertility as an illness <i>Yes / No (%)</i>	n.a.	62.9 / 37.1
Patients' experiences in their own clinic with:		
- Information provision <i>Contradictory / General / Clear (%)</i>	5.2 / 28.0 / 66.7	n.a.
- Patient involvement <i>Never / Sometimes / Always (%)</i>	9.1 / 51.9 / 39.0	n.a.
- Continuity of physicians <i>Always different / One lead physician / Always the same physician (%)</i>	20.3 / 59.0 / 20.7	n.a.

^a Low = Primary or lower vocational education; Middle = secondary or intermediate vocational education; high = higher professional education or university.

^b Net monthly family income of the couples was categorized according to the level of the Dutch modal income in Euros: <2500, at or below Dutch modal income; ≥ 2500 , ≥ 1.5 times Dutch modal income.

^c Assisted reproductive technology (ART), encompassed IVF, IVM, ICSI, cryopreservation and testicular sperm extraction.

^d Non-ART included ovulation induction and intrauterine inseminations with or without controlled ovarian stimulation.

Table 3
Patients' and health insurers' relative importance per attribute level

Attributes	Level	Patients		Health insurers	
		Coefficient (95% CI)		Coefficient (95% CI)	
Pregnancy rate	Per percent	0.202	(0.194-0.211)*	0.162	(0.139-0.186)*
Information provision	1.Contradictory information	-	-	-	-
	2.Only general information	0.982	(0.865-1.099)*	0.605	(0.288-0.922)*
	3.Clear and customized information	1.606	(1.483-1.729)*	1.109	(0.801-1.418)*
Patient involvement	1.Never	-	-	-	-
	2.Sometimes	0.811	(0.691-0.930)*	0.233	(-0.078-0.544)
	3.Always	1.047	(0.927-1.168)*	0.713	(0.393-1.033)*
Continuity of physicians	1.Seeing a different physician almost every visit	-	-	-	-
	2.Having one lead physician	0.342	(0.222-0.462)*	0.321	(0.009-0.634)*
	3.Always seeing your own physician	0.658	(0.538-0.778)*	0.682	(0.369-0.996)*
Additional costs per cycle	Per €100,-	-0.409	(-0.478- -0.340)*	-0.993	(-1.290- -0.697)*
Interactions					
Costs * female age > 36 yrs		0.081	(0.024-0.138)*	-	-
Costs * Dutch ethnicity		0.149	(0.065- 0.233)*	-	-
Costs * high family income		0.156	(0.093-0.220)*	-	-
Costs * ART treatment type		0.064	(0.012-0.116)*	-	-
Costs * age per 10 years		-	-	0.161	(0.094-0.228)*

Coefficients were calculated using generalized estimating equations with logistic regression analysis.

* p<0.05

Table 4

Willingness-to-pay for higher pregnancy rates and more patient-centred care for both patients and health insurers

		Improvement of patient-centred care					
		1% higher pregnancy rates		Step 1		Step 2	
		n	Median	(range)	Median	(range)	Median (range)
PATIENTS							
Age	< 36 years	461	€107	(36-187)	€735	(249-1286)	€463 (157-810)
	≥ 36 years						€554 (188-969)
Ethnicity	Dutch	359	€80	(36-107)	€549	(249-735)	€346 (157-463)
	Non-Dutch	102	€117	(42-187)	€808	(291-1286)	€509 (183-810)
Income	Low income	401	€107	(49-187)	€735	(340-1286)	€463 (214-810)
	High income	60	€49	(36-79)	€336	(249-540)	€212 (157-340)
Treatment type	Non-ART	99	€59	(36-77)	€403	(249-526)	€254 (157-331)
	ART	362	€107	(47-187)	€735	(322-1286)	€463 (203-810)
Examples of patient profiles	≥ 36 years, Dutch, high income, ART	148	€80	(36-117)	€549	(249-808)	€346 (157-509)
	< 36 years, Dutch, low income, non-ART	313	€107	(41-187)	€735	(281-1286)	€463 (177-810)
HEALTH INSURERS		48	€187		€1286		€969
		23	€49		€340		€256
Examples of health insurer profiles	30 years	45	€60	(27-150)	€340	(155-847)	€191 (87-477)
	50 years						€399 (182-994)
Examples of health insurer profiles	30 years	13	€32		€179		€101
	50 years	17	€86		€487		€274

for heterogeneity of our study population. Therefore, we were able to quantify the preferences of our study participants most optimally. Furthermore, although we performed our study nationally and within one healthcare area, our results might be stimulating for others as well. Within an international fertility care setting, comparable results could even be expected as research has shown that patients across Europe have similar views regarding patient-centred care.²⁴

A number of limitations should also be taken into account when interpreting our results. The first limitation considers the DCE design in itself, because we cannot guarantee that other attributes, which we did not include in our study, are irrelevant. For example the travel time to a clinic or safety of treatments might be important for patients or health insurers as well when choosing a clinic. We did not include these attributes, because we wanted to compose clear and easy to follow scenarios. A maximum number of five attributes is suggested^{22,25} and we therefore selected the most important attributes from the literature.^{12,13} Second, the DCE scenarios will always be hypothetical for our study participants and it is unclear whether they would make other choices in real life. We tried to prevent this potential bias by grounding the definition of our attributes and levels on both the literature and the opinion of an expert panel. Moreover, we performed a pilot study among patients and a health insurer to test the validity of our questionnaire. Finally, we added a clear addendum to the questionnaire to instruct the study participants most optimally. A third limitation concerns the levels of the cost attribute, which were based on the Dutch fertility care setting and would obviously differ within other countries or different healthcare areas. Therefore, we suggest to interpret the willingness-to-pay for more patient-centred fertility care as a relative amount and consider it in relation to the willingness-to-pay of higher pregnancy rates, reflecting the effectiveness of fertility care.

Although this is the first study determining the monetary value of patient-centred care, it touches on the results of some other studies about the relevance of patient-centredness. In the area of fertility care, Ryan showed that infertile patients were willing to pay for a good staff attitude, continuity of physicians, shorter waiting times and follow-up support.¹⁵ Moreover, Van Empel and colleagues found that patients were willing to trade off up to a third of their pregnancy rate for the improvement of different elements of patient-centred care (e.g. more information provision).¹⁷ This corresponds to our findings where patients were willing to trade of more than four percent of their chance to get pregnant for the second improvement step of patient-centred care (i.e. $\text{€}463 / \text{€}107 = 4.3$). Comparable results were also found within other healthcare areas. In a systematic review on patients' choices in healthcare, several patient-centred aspects such as better staff's competence, higher accessibility of the clinic, optimal communicating skills of the physician, and being able to see the same doctor were brought forward as

elements influencing patients' choice for a provider or clinic.²⁶ However, as the relative importance of these factors was not studied, translating these findings into implications for daily clinical practice is difficult.

The results of our study ask for some recommendations for different stakeholders in healthcare. First, our study results should be an absolute motivator for professionals to monitor and improve their clinic's level of patient-centred care, because patients appear to choose for a clinic with a more patient-centred approach. Although measuring patient-centredness might seem complicated, initiatives in different healthcare areas have shown that objectively measuring patients' experiences with care is possible.^{12,27,28} Subsequently, publically publicizing clinics' results on their level of patient-centredness could initiate competition among clinics, stimulating the improvement of patient-centred care even more.²⁹ Second, our results suggest that health insurers should take clinics' levels of patient-centred care more into account when purchasing care as they placed less importance on patient-centred care than their customers did. This might be due to the different focuses of patients and health insurers. Where patients take into account their own perspective, health insurers have to cover the wishes and preferences of the entire population. Our results might therefore be helpful for health insurers, as we provided them with a clear picture of the preferences and needs of the infertile patient. Our final recommendation touches on the actual payment for more patient-centred care. Our results suggests that patients are willing to pay an additional fee for a clinic providing more patient-centred care. Although different studies have shown that 'fee for performance' does not enhance the improvement of quality of care^{30,31}, the effect of introducing additional copayments for more patient-centred care has never been debated. It might, for instance, increase patients' autonomy. Currently, patients are restricted to use care that is already purchased by their health insurer. When introducing additional copayments, patients would be able to use their own financial resources and directly choose a clinic matching their preferences and wishes regarding patient-centred care. Moreover, it appears to be in line with a recent recommendation of the World Health Organization to increase patients' copayments in case more than six percent of the gross national product (GNP) is spend on healthcare.³² In the Netherlands, 11.9 percent of the GNP is spend on healthcare, indicating the need for a debate on the reimbursement of care expenses. Of course, our suggestions considering copayments for more patient-centred care are very premature. For example, ethical, social and practical issues should be considered first and more research is needed to study the feasibility of introducing these payments. With this study, we have made a first initiative to actually determine the importance of patient-centredness by calculating its monetary value and relating it to the monetary value of another important outcome measure, i.e. the effectiveness of

care. Hopefully, our results will increase the motivation of professionals, health insurers and policy makers to aim at the improvement of patient-centred care, as it corresponds to the preferences and wishes of the most important stakeholder in healthcare, the patient.

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WHAT I WANTED
WAS A PREGNANCY
PLEASE, DO NOT TELL ME
THAT IT WILL ALL BE
WHAT I EXPECTED
ANSWER THIS QUESTION
RING THE FIVE YEAR
ROUGH DIFFERENCE
HOW IT

JUST BE A MISTAKE
OUR BODY NEEDS MORE
DOCTOR HAD TOLD ME, BUT DOCTOR
I CONFIRMED WHAT HER COLLEAGUES
TO CONTINUE MY TREATMENT. THEY
WERE ALSO FIRM IN THEIR STATEMENTS
THE DOCTOR AND THERE WAS NOTHING

INSECURE. I HAD TO SHARE MY EXPERIENCE WITH PATIENTS WHO WERE ALREADY PRESENTING
PRESSURE OF THEIR PREGNANCIES TOGETHER. THAT'S GOOD FOR FERTILITY. IT WAS VERY HARD FOR ME TO SEE ALL THESE BIG BELLYS
ED MYSELF RETURN TO THE WAITING ROOM FOR A FEW MORE MINUTES
RE I WAS, SITTING NEXT TO A MOTHER WITH A TWO YEAR OLD CHILD
WANTED TO PUT MYSELF IN HER SHOES AND FELT REALLY NERVOUS
I REALIZED HOW PRESSURE. FOR EXAMPLE, IT HAPPENED
POINT OUT THE OBVIOUSLY, THE DOCTOR WAS NOT AVAILABLE
HAD MY OWN CALM BEFORE I ENTERED THE ROOM
NTRIAL. IT FELT LIKE ALL DOCTORS HANDS

IMPROVING PATIENT-CENTRED FERTILITY CARE

ALREADY FEELING PSYCHOLOGICAL
EVER HAVING PRODUCED
CONFUSING WE DID NOT
OUT IN A MAGAZINE. OUR
THE OPPOSITE IS TRUE AND
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COMMUNICATING MY HUSBAND
NOT OF SMALL THINGS. MY DOCTOR
TREATMENT TO BUT MY DOCTOR
WHAT YOU WOULD OF COURSE
LIKE TO SHARE ABOUT MY
Y. YES, WE ONLY GOT PREGNANT
BEFORE, IT EVEN MORE
NICE AND ON THIS
ASKED ME WAS DOING
AID. HE SAYS YOU
PREFERRAY ANY
GAPMENT

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BE MORE IMPORTANT
BUT JUST LISTEN
TO HIS INTENTIONS WE
NEED APPROACH. DO
CAN ALSO SUPPORT
TREATMENT FOR
EXPERIENCES
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BE A JUST T THING
RE THE SS HAD
TO T NOW

"WE WILL GET YOU PREGNANT, LADY!" THESE WERE LITERALLY THE WORDS OF THE DOCTOR WHO WOULD MAKE SURE THAT I GOT WHAT I WANTED: A BABY. OF COURSE, I KNEW THAT THE CHANCE TO ACHIEVE PREGNANCY WAS FAR FROM GUARANTEED, BUT IT USED TO SOUND LIKE: "PLEASE, DO NOT THINK TOO MUCH ABOUT IT. YOUR GYNÁECOLOGY WILL MAKE SURE THAT IT WILL ALL TURN OUT WELL." BUT NO, THIS WAS DEFINITELY NOT WHAT I EXPECTED FROM A PATIENT-CENTRED CARE? I CAN ANSWER THIS QUESTION WITH A CATEGORICAL NO. MY HUSBAND AND I EXPERIENCED DURING THE FIVE YEARS THAT WE WERE WAITING FOR A CHILD DURING THESE YEARS, WE WENT THROUGH DIFFERENT POSITIVE AND NEGATIVE EXPERIENCES. TO MAKE IT MORE UNDERSTANDABLE HOW IT IS TO BE A PATIENT WITH INFERTILITY, I WILL SHARE SOME OF MY EXPERIENCES. AFTER I HAD UNDERGONE A LAPAROSCOPY TO FIGURE OUT WHY I WASN'T GETTING PREGNANT, A NEW APPOINTMENT WITHIN TWO WEEKS TO START UP A NEW TREATMENT WAS SURPRISINGLY ANSWERED: 'THIS MUST BE A MISTAKE, BECAUSE IT'S TOO EARLY AFTER SURGERY. OBVIOUSLY, YOUR BODY NEEDS MORE TIME TO RECOVER.' BUT THAT WAS REALLY WHAT THE DOCTOR HAD TOLD ME. BUT BEFORE I COULD GO HOME, MY COLLEAGUE, AGAIN, SHE ONLY CONFIRMED WHAT HER COLLEAGUE HAD SAID. I HAD TO RETURN WITHIN TWO WEEKS TO CONTINUE MY TREATMENT (AND I HAD TO TALK TO THE SECRETARIES, WHO WERE ALSO FIRM IN THEIR STATEMENTS. I COULD NOT GO HOME. THERE WAS NO PROBLEM TO SEE THE DOCTOR AND THERE WAS NOTHING WRONG WITH ME. I WAS VERY INSECURE AND HAD STRESSED ME OUT, WHICH OBVIOUSLY OFTEN HAD TO SIT NEXT TO PATIENTS WHO WERE ALREADY PREGNANT AND TALKING ABOUT THE PROGRESS OF THEIR PREGNANCIES TOGETHER. THAT'S GOOD FOR INFERTILITY. IT WAS VERY HARD FOR ME TO SEE ALL THESE BIG BELLYS. THE DOCTOR ASKED ME TO RETURN TO THE WAITING ROOM FOR A FEW MORE MONTHS. THERE I WAS, SITTING NEXT TO A MOTHER WITH A TWO-YEAR OLD CHILD. I FELT I WANTED TO PUT MYSELF IN HER SHOES AND FELT REALLY MISERABLE. BUT IT WAS NOT REALLY IMPRESSIVE. FOR EXAMPLE, IT HAPPENED SEVERAL TIMES THAT I HAD AN APPOINTMENT. OBVIOUSLY, THE DOCTOR WAS NOT AWARE OF THE FACT THAT I HAD READ MY MEDICAL RECORD BEFORE I ENTERED THE ROOM. ALSO, THE INFORMATION WAS CONTRADICTORY. IT SEEMED LIKE ALL DOCTORS HANDLED OUR CASE DIFFERENTLY. IT SCARED ME A LITTLE BIT, AS I ALREADY FELT PSYCHOLOGICAL PRESSURE. I FELT THAT MY DOCTORS WERE ALL POINTING IN THE SAME DIRECTION. I FELT THAT OUR OWN DOCTOR SHOULD NEVER HAVE INTRODUCED THE IVF TREATMENT OPTIONS. VERY CONFUSING, AS WE DID NOT KNOW WHAT THE NEW TREATMENT I READ ABOUT IN A MAGAZINE. OUR DOCTOR HAD SAID THAT OUR HOSPITAL, WHILE EXACTLY THE OPPOSITE WAS TRUE ACCORDING TO THE CRITERIA ELIGIBLE FOR THIS TREATMENT BEFORE. EVENTUALLY, I WAS TOLD THAT I WAS BEING RECOMMENDED FOR IVF TREATMENT. MY HUSBAND AND I WENT FOR AN ULTRASOUND CHECK-UP. A LOT OF SMALL FOLLICLES WERE VISIBLE. THE DOCTOR TOLD ME: 'YOUR APPOINTMENT TO ME, BUT MY DOCTOR JUST SAID YOU LOOKS FINE, BUT THIS IS NOT WHAT YOU NEED OF COURSE!' WELL, THAT WAS NOT WHAT I WANTED TO HEAR. I WOULD LIKE TO SHARE, IS ABOUT MY ADMIS- SION TO THE HOSPITAL DURING MY PREGNANCY. YES, WE FINALLY GOT PREGNANT AFTER 5 YEARS. BUT BEN J. COHLEN ENTERED MY ROOM: 'IT IS VERY NICE AND QUIET ON THIS SECTION!' HE SAID. HE ENTERED MY ROOM AND ASKED ME HOW I WAS DOING. I TOLD HIM I WAS 'ALLOWED' TO GO HOME, HE SAID. HE OBVIOUSLY THOUGHT THAT I WAS 'ALLOWED' TO GO HOME. I WOULD HAVE PREFERRED TO STAY ANOTHER DAY. A PERFECT EXAMPLE OF 'TALKING ABOUT THE PATIENT', INSTEAD OF

ALEIDA G. HUPPELSCHOTEN

JOHANNA W.M. AARTS

INGE W.H. VAN EMPEL

BEN J. COHLEN

JAN A.M. KREMER

WILLIANNE L.D.M. NELEN

CHAPTER 7

FEEDBACK TO PROFESSIONALS ON PATIENT CENTRED

FERTILITY CARE IS INSUFFICIENT FOR IMPROVEMENT:

A MIXED-METHOD STUDY

FERTILITY AND STERILITY 2013; 99: 1419-1427

Abstract

Objectives

To determine the effect of audits and feedback on the level of patient-centredness in fertility care, and getting more in-depth understanding of professionals' view on patient-centred care and achieving improvements.

Methods

In the quantitative part of this mixed method study, patient questionnaires were used in 15 Dutch fertility clinics among women who were under treatment for infertility. After auditing the level of patient-centredness of care in 2009, using the PCQ-Infertility questionnaire, feedback was provided to the clinics by a personalized paper-based feedback report. We measured patients' reported differences in the level of patient-centred fertility care between 2009 and 2011. In the qualitative part, we performed semi-structured in depth interviews among fertility care professionals. Professionals' view on improving patient-centred fertility care was arranged into Hibbard's framework for behavior change.

Results

Multilevel regression analysis showed no significant differences between the overall levels of patient-centredness in 2009 and 2011. Qualitative research showed that professionals' urge to change and their ability to translate feedback were suboptimal to achieve professionals' behavior change.

Conclusions

Audits and feedback alone are not enough to improve the level of patient-centredness in fertility care. Increasing professionals' desire to change and their ability to translate feedback about their performance into an optimal quality improvement strategy appear to be the key issues.

Background

Patient-centredness has gained attention as an important dimension of quality of care.^{1,2} Health-care organizations increasingly focus on integrating patients' preferences and needs into the delivery of health care, and they guide delivery by their patients' values; this can be considered a definition of patient-centred care.^{2,3} Providing patient-centred care has several presumed benefits, such as increasing both the patients' quality of life⁴ and the professionals' job satisfaction.⁵⁻⁷ Areas of health-care such as fertility care, which are associated with a high emotional impact and intensive treatment periods, especially could benefit from patient-centred care.^{8,9} The stigmatizing character of infertility^{10,11} and the high dropout rates from treatment¹² are valid reasons for fertility professionals to consider the importance of patient-centred. Moreover, a lack of patient-centred care has been one of patients' main non-medical reasons for changing fertility clinics.^{13,14}

In that market forces and competition between clinics are everyday aspects of modern health care, fertility clinics should be motivated to optimize their care toward a more patient-centred approach.¹⁴ Yet improvement is clearly needed in patient-centred care.^{15,16} Because professionals in fertility care underestimate the importance of patient-centredness^{13,17} and have difficulty adequately estimating their own performance¹⁷, they must be motivated to address these aspects. Tailored improvement strategies are thus needed for fertility clinics to adopt a more patient-centred approach.

A plethora of strategies exist for improving patient-centredness of care, but these strategies have rarely been evaluated in the fertility-care setting yet. In general, audits and feedback are key components of most quality-improvement projects.¹ However, when there is no appropriate measurement tool (i.e., an audit), no accurate baseline level of patient-centredness can be established. Without any feedback about the audit's results, professionals may have difficulty understanding their patients' preferences, wishes, and needs.^{1,17} Also, it is unknown whether professionals have the knowledge, skill, time, and ability to translate feedback to optimal quality improvement strategies. Moreover, for feedback to be effective, some studies have underlined that it must be part of an intervention, consisting of multiple components such as educational outreach visits and patient-mediated interventions.¹⁸⁻²⁰ Others have doubted the effectiveness of such interventions in ensuring the implementation of patient-centredness throughout a clinic.^{1,21}

Our study measured the effect of auditing and feedback on the patient-centredness of fertility care by use of a quantitative approach. Then, in a qualitative study, we gained insight into the professionals' views of patient-centred fertility care and which aspects were seen as important for its improvement. The findings of

both the quantitative and qualitative studies can be applied to design a targeted strategy for the quality improvement of patient-centredness in Dutch fertility care.

Materials and methods

Study design

A mixed-method study design combining both qualitative and quantitative data not only provides a more comprehensive, in-depth understanding of the research objectives but also has a complementary function.²²⁻²⁴ The quantitative part of our study included patients, and the qualitative part focused on the fertility care professionals. The institutional ethics committee of Radboud University Nijmegen Medical Centre provided ethical approval for this research to proceed.

Quantitative part

In the quantitative part of this study, the effect of an audit and feedback on the level of patient-centred fertility care was determined in 2011, two years after clinics had been audited and received the feedback.

Setting

Baseline measurement (T0) of this study was nested within a study to validate a questionnaire measuring the level of patient-centredness of fertility care.¹⁵ A total of 29 Dutch fertility clinics participated in the validation study in 2009, which showed that there is room for improvement regarding patient-centred fertility care in the Netherlands.¹⁵ Data from 15 large and medium-sized clinics were selected for this study. In the Netherlands, a total of 13 large clinics are licensed to perform all kinds of fertility treatments; the medium-sized “transport” clinics must refer their patients to these larger clinic for the laboratory phase and embryo transfers of the in vitro fertilization (IVF) and intra-cytoplasmic sperm injection (ICSI) treatments.

Study population

The study population consisted of women undergoing infertility treatment in one of the 15 participating Dutch fertility clinics. All women who participated underwent at least one cycle of medically assisted reproduction (MAR) (e.g., ovulation induction, intrauterine insemination, IVF, or ICSI). Previous studies had shown that patients with positive treatment results are more likely to maintain a positive perspective on their care than patients who have had a negative treatment result.^{15,17} As this strong association between the treatment outcome

and the patient's experiences would bias our results, we excluded all patients who had achieved pregnancy during the study period from our analyses.

Primary outcome measure: patient-centredness

We used the Patient-Centredness Questionnaire–Infertility (PCQ–Infertility), which is an instrument to assess a clinic's level of patient-centredness by measuring patients' experiences with fertility care. The questionnaire consists of 46 items, covering seven subscales: Accessibility, Information, Communication, Respect for Patients' Values, Continuity and Transition, Patient Involvement, and Competence.¹⁵ The higher the score on the total PCQ scale or one of the subscales (range: 0–3), the higher the level of patient-centredness. A baseline measurement of this study was part of the validation study of the PCQ–Infertility; some changes were made afterward to improve the reliability and validity of the questionnaire, but these differences were small (i.e., rephrased words and sentences).

Intervention: audit and feedback

To audit the level of patient-centredness of Dutch fertility care, infertile women were asked to share their experiences with fertility care by filling out the PCQ–Infertility. After this audit, all hospitals received a personalized paper-based feedback report that consisted of clinic's mean results on the level of patient-centredness (i.e., total score and subscale scores). The results were presented in relation to all participating clinics (anonymously)—that is, benchmarking. To identify the aspects of care with the highest priority for improvement (e.g., information provision or communication), quality improvement (QI) scores for all questionnaire items (care aspects) were calculated per clinic and presented in the feedback report. The higher a QI score, the more need there is for improvement. For more information on PCQ and QI scores, the reader is referred to Van Empel *et al.*¹⁵ After receiving the report, clinics had the liberty to change or adjust the aspects of care that needed improvement according to their patients.

Data collection

T0-measurement

The clinics extracted from their diagnosis treatment combination (DBC) coding system the addresses of patients who underwent MAR in their clinic between April and June 2009. With the information from the clinics, we randomly selected 25 to 75 patients (depending on clinic's size) to invite to participate. Participation was voluntary and anonymous. Patients were sent a reminder card 3 weeks after the initial mailing. Another two weeks later, the non-responders

received a reminder with a copy of the questionnaire. In January 2010, all hospitals received the personalized feedback report.

T1-measurement

Two years later, selection of a new cohort of patients was performed in the same way as in T0. The questionnaire distribution was executed using a multiple mode method, as it has been shown that combining an Internet-based questionnaire with a papers-based follow-up improves the quality of data and is less expensive than a postal survey alone.²⁵ Included patients received a letter and were invited to complete the PCQ-Infertility questionnaire online, which was accessible through a personal code. A reminder card was sent after three weeks. Non-responders received a paper-based version of the PCQ-Infertility another two weeks later. In the meanwhile, a small process evaluation was executed to determine what organizational changes could be associated with a possible change in patient-centredness. To this end, the representative gynaecologists of all 15 clinics received a questionnaire with questions about the major changes they had made within their clinic between T0 and T1, both based on the feedback report and apart from the feedback report (e.g., clinic's rebuilding).

Data analysis

First, differences in patient characteristics between T0 and T1 were determined to explore whether case-mix adjustment was necessary. Subsequently, patient-centredness scores at T0 and T1 were compared with adjustment for clusters of patients within the same clinic. For this purpose, a multilevel multivariate regression analysis was performed in which the PCQ-Infertility's total and subscale scores were considered as the dependent variables. Additionally, we focused on the clinics that reported major changes based on the feedback report. As we had expected an improvement in PCQ-Infertility scores to be found within these clinics, we explored the results of these clinics separately.

Significance for all analyses was set at $P < 0.05$. However, as we are reporting about differences between patient-centredness scores, it is important to define a change that can be considered clinically important, that is, a minimally important difference (MID).²⁶⁻²⁸ Therefore, we considered differences of 0.3 or more (i.e., 10% of the maximum difference) as clinically relevant for the present study's purpose.²⁶⁻²⁸ Quantitative analyses were performed using SPSS (version 18.0 for Windows, SPSS Inc.).

Qualitative part

The aim of the qualitative part of this study was to understand the effect of audit and feedback on the level of patient-centredness. Therefore, this part focused on professionals' views on patient-centred fertility care as well as on barriers and facilitators for its improvement.

Study population

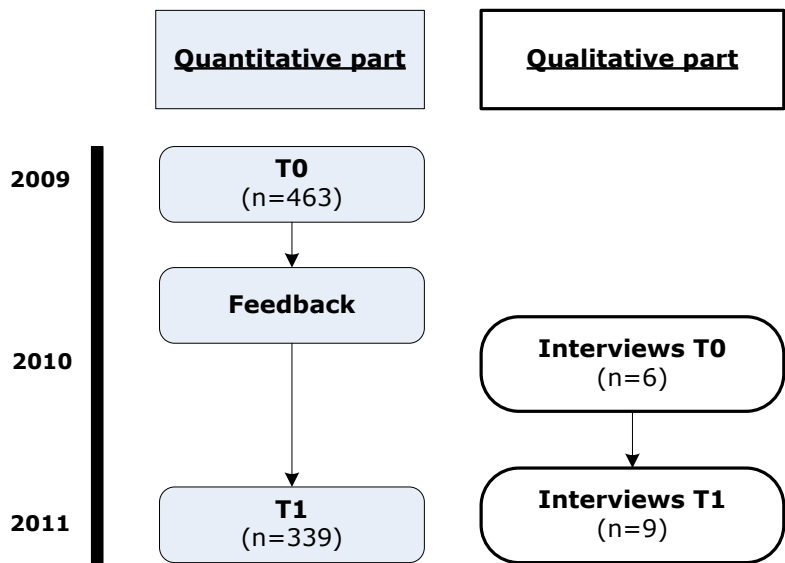
A total of ten gynaecologists, two fertility nurses, and three quality officers from ten different Dutch clinics participated. We performed semi-structured interviews with these professionals in 2010 and 2011.

Data collection

We performed semi-structured interviews and used Hibbard's theoretical consumer choice model.²⁹ According to this model, a series of events should take place before someone changes his or her behavior. Translating this toward the current study setting (i.e., changing behavior to achieve a more patient-centred approach in fertility care), [1] professionals must be *aware* of what patient-centred care is and that there is room for improvement; [2] they should have *knowledge* about the way they (i.e., their clinic) provide patient-centred care and how to translate this into an action plan; and [3] they should *feel* that improving patient-centred fertility care is important and want to change. Only after these steps in awareness, knowledge and attitude have been achieved [4] professionals can really *change their behavior* toward improving patient-centred care.²⁹

We performed the interviews in two phases. First, one author (J.A.) performed interviews a few months after feedback from the T0 measurement (spring 2010). During these interviews, we focused mainly on the first two steps of Hibbard's choice model. Two years later, after the professionals had had the opportunity to change their clinic, another author (A.H.) performed the interviews for the T1 measurement (summer 2011). These interviews were mainly focused on the third and fourth step of Hibbard's choice model. New interviews were performed until saturation was achieved and no new themes came up. A flowchart of both the quantitative and qualitative part of the study is presented in Figure 1. All interviews were tape recorded with the participants' consent and were transcribed verbatim.

Figure 1
Schematically flowchart of the study



Data analyses

We performed a thematic content analysis with constant comparison.³⁰ One researcher (A.H.) performed open coding on selected transcripts to derive a list of themes emerging from the analysis. Subsequently, a second researcher (J.A.) used this list of themes to perform selected coding on all interviews. Differences in interpretation were small, and consensus was achieved promptly. Then the two researchers (A.H. and J.A.) categorically merged these codes and fitted them into the four steps of Hibbard’s theoretical consumer choice model—awareness, knowledge, attitude, and behavior—to understand what aspects are important to achieve behavior change among these professional. These aspects would be considered crucial in designing projects to improve patient-centredness.

Results

Quantitative: Effect of audit and feedback on patient-centredness

At T0, 759 patients received the PCQ-Infertility, of whom 575 filled out the questionnaire (response rate: 76%). A total of 462 questionnaires were eligible for analysis, as 112 patients were pregnant (19%) and thus excluded. At T1,

448 out of 780 patients completed the PCQ-Infertility (response rate: 57%), of whom 109 patients (24%) were pregnant. Therefore, 339 questionnaires were eligible for analyses. Table 1 presents all patient characteristics and shows that the participating patients at T0 and T1 were statistically significantly differed in the following three characteristics: childlessness ($P=.02$), diagnosis ($P=.01$), and type of treatment ($P\leq.01$). These characteristics were considered as case-mix adjusters for further analyses.

Table 1

Patient characteristics stratified by 2009 and 2011

Characteristic	2009 n=463	2011 n=339	p-value
Median age (years, range)	33 (20-45)	33 (23-44)	0.27
Ethnic background			
Dutch / non-Dutch (%)	84.8 / 15.2	86.8 / 13.4	0.54
Level of education			
Low-medium / high ^a (%)	56.0 / 44.0	53.3 / 46.7	0.46
Median duration of infertility (months, range)	36 (2-174)	34 (3-133)	0.34
Childless couples (%)	70.2	77.8	0.02*
Diagnosis			
Female factor / male factor / other (%)	25.4 / 29.6 / 45.0	30.3 / 20.1 / 49.7	0.01*
Treatment type			
ART ^b / non-ART ^c (%)	63.1 / 36.9	52.6 / 47.4	<0.01*

^a Low = primary or lower vocational education; middle = secondary or intermediate vocational education; high = higher professional education or university.

^b Assisted reproductive technology (ART), encompassed IVF, ICSI, cryopreservation and testicular sperm extraction.

^c Non-ART included ovulation induction and intrauterine insemination with or without controlled ovarian stimulation.

* Significant difference ($p<0.05$) between 2009 and 2011 using *t*-tests for continuous variables and chi-square tests for dichotomous variables.

Table 2 presents the results of the multilevel multivariate regression analysis. When adjusted for the aforementioned case-mix adjusters, no statistically significant differences in PCQ-Infertility total scores were found between T0 and T1 ($P=.13$; 95% confidence interval [CI], -0.01 – 0.10). In three of the seven subscales, statistically significant differences between T0 and T1 were found. The PCQ-Infertility subscale Accessibility showed a statistically significant improvement in time ($P\leq.01$; 95% CI, -0.37 to -0.13), whereas the scores on the subscales Continuity and Transition ($P\leq.01$; 95% CI, 0.07 – 0.23) and Competence ($P=.03$; 95% CI, 0.01 – 0.12) were statistically significantly lower at T1 than at T0. Nevertheless, none of these differences were considered clinically relevant (beta <0.3).

Table 2
Differences in patient-centredness, adjusted for childlessness, diagnosis and treatment type

	2009 n=463	2011 n=339	Beta	(95% CI)
Mean PCQ-Infertility total score	2.23	2.19	0.05	(-0.01 – 0.10)
Mean PCQ-Infertility subscale scores				
Accessibility	2.11	2.37	-0.25	(-0.37 – -0.13)*
Information	2.15	2.13	<0.01	(-0.08 – 0.08)
Communication	2.54	2.52	0.04	(-0.04 – 0.11)
Respect for patients’ values	2.05	1.94	0.09	(-0.01 – 0.20)
Continuity and transition	1.97	1.85	0.15	(0.07 – 0.23)*
Patient involvement	2.39	2.30	0.08	(-0.01 – 0.18)
Competence	2.48	2.42	0.06	(0.01 – 0.12)*

* Significant difference ($P<0.05$) between 2009 and 2010 using multilevel multivariate regression analysis.

Process evaluation

The questionnaire sent to the participating gynaecologists demonstrated that all gynaecologists studied the feedback report in detail and all but one discussed it within the clinic’s fertility team. Based on the results of the feedback report, five gynaecologists made major changes in their clinic between T0 and T1. Most changes were seen on the domains Information Provision (e.g., rewriting brochures) and Continuity and Transition (e.g., assigning one gynaecologist to be mainly responsible for an infertile couple). Of the five clinics who initiated an improvement project based on the feedback report, only one clinic improved over time on their mean total PCQ-Infertility score (1.72 to 1.89), two clinics had PCQ-Infertility scores that were comparable at T1 and T0, and the other two clinics had scores that declined over time (i.e., 2.17 to 2.08, and 2.42 to 2.22).

To provide a complete picture of all clinic changes, we also asked which major parts of the clinics had been changed in the past 2 years *apart* from the results of the feedback report. Seven gynaecologists reported one or more such changes, of which most changes ($n = 5$) concerned the rebuilding of the clinic or a move to a new location.

Qualitative: how to achieve behavioral change in professionals?

The interviews identified a range of opinions related to patient-centred fertility care and how improvement projects should be designed. We selected a total of 975 statements from the interviews and divided them into 152 different codes. These codes were subdivided into 17 categories fitting the four steps of Hibbard's theoretical consumer choice model. Table 3 provides an overview of all codes that emerged more than five times from the interview analyses. This table also presents the classification of these codes into the different steps of Hibbard's choice model. Most important findings are presented per step of Hibbard's choice model.

1. Awareness

According to the first step of Hibbard's choice model, the professionals formulated definitions about patient-centred fertility care. First, patient-centred fertility care was stated to be about and performed around the patient as an individual, just as it is defined by the Institute of Medicine.³ For example:

"Patient-centredness is particularly care in the way that the patient sees it. So, through the patients' eyes. She can rate it with a report mark, or just tell us in words what she thinks. It is important to get that information in a direct conversation with the patient." (interview no. 7)

Others gave more concrete answers, summarizing items that comprised patient-centredness according to them. For example:

"What is patient-centredness? Well, I can think about a lot of things... You can think about accessibility by phone or enough parking places or the attitude of the nurses and doctors." (interview no. 10)

2. Knowledge

Relatively few statements were made about this topic, in which we explored professionals' knowledge about their actual provision of patient-centred care and difficulties they faced in daily practice. First, a number of respondents reported that it is difficult to estimate their own performance accurately. For example,

"The results about the waiting times were disappointing to us. Obviously, at some points we are totally beside the mark: we think that we provide really good care, but through the eyes of the patients, we don't." (Interview no. 1)

Second, respondents noted that differences between clinics and between professionals within the same clinic complicated the continuous provision of patient-centred fertility care. For example, "I also realize that not every clinic is comparable with our clinic. For example:

"I also realize that not every clinic is comparable with our clinic. For example, if you compare a university hospital to us [general hospital], things will be organized totally differently."
(Interview no. 3)

3. Attitude

Most professionals realized that it is important to improve patient-centred fertility care. Several reasons were put forward:

"I don't have any experiences with this kind of improvement projects, but I am open to new ideas, as will all of my colleagues be. So, you are more than welcome!" (Interview no. 8)

"I think that when you take a look at our clinic's business plan, it says something like: 'We want to be the best hospital of the whole country!'" (Interview no. 12)

"Transparency about clinics' performance is important.... How is a clinic certificated? What are their results? We have to develop a quality label and put that on a clinic when it meets the criteria." (Interview no. 6)

To summarize, first, most professionals' attitude toward patient-centredness could be defined as "open": they believed in improving the level of patient-centredness and wanted to think about and discuss potential changes. Second, professionals mentioned that they wanted to improve their performance to become the best clinic in the region or the country. They suggested that publically publishing the study results would increase their desire to change, as no clinic wants to be the worst performing clinic.

4. Behavior

Professionals provided many suggestions on strategies for the improvement of patient-centred fertility care. In general, professionals preferred to receive feedback on their performance. Subsequently, they felt this feedback needed to be discussed with the complete professional team. The format of feedback had to consist of several specific aspects, as these interviews showed:

"I prefer visual feedback, because than you can really see it. You can see immediately how you perform and that is really clear." (Interview no. 11)

"I would prefer to receive real and concrete examples. For instance, patients state that they want to have an overview of all their treatments... .. then you [researcher] can provide us with a good overview that we can use immediately." (Interview no. 10)

"If you really want to expand this research, you have to engage some kind of national consultancy team that can help Dutch fertility care centres. They should visit the clinics after they received the feedback report and provide them with the most efficient ways of improving the level of patient-centredness. I would even pay for that service." (Interview no. 1)

In short, first, the professionals preferred visual feedback (i.e., tables, graphics, pictures). Second, they wanted the feedback to be as specific as possible and to represent their own clinic. Third, the professionals needed support with practical translation to an improvement plan and its execution. This support appeared to be particularly needed: lack of time was quoted as the most important barrier to improving the patient-centredness of care. Also, having a committed medical team was found to facilitate the process of improving patient-centred fertility care.

Table 3
Classification of 152 different codes according to the four steps of Hibbard’s theoretical consumer choice model

Hibbard’s steps	Categories	No.	Codes
Awareness (225)	<i>Through the patients’ eyes</i>	17	Appreciation from patients
		15	Insight in what people think
		14	Patients’ wishes and expectations
		8	All about the patient
		7	In conference with a patient
	<i>Professionals’ definition of PC-care</i>	6	Through the patients’ eyes; Patient is welcome
		5	Patients’ opinion; Report mark for performance
		16	Communication of the team
		13	Seeing your own leading physician
		9	Different professionals provide the same care
	<i>PC-care vs. pregnancy rates</i>	8	Clinic’s culture
		7	Several factors influence delivering good care
		5	More opportunities to make an appointment; Short access times; Good information provision
		7	Pregnancy rates are most important
		5	Child wish is core of the existence
	<i>Clinic’s differences</i>	12	Differences between hospitals
		7	Evaluation of different staff members
Knowledge (79)	<i>Different interpretations</i>	17	Different interpretation physician and patient
		7	A high standard for patient-centred care
	<i>PC-care as a quality mark</i>	7	A high standard for patient-centred care
	<i>Not being open for PC-care</i>	5	Comments on the way of working
	<i>Extrinsic urge to improve</i>	31	Compare to national scores
		8	Competing with other hospitals; Aiming at the highest goal
		6	Preserving the top; Distinguishing yourself
		5	Publishing the results; Market forces; Preventing patients switch to other clinics
	<i>Intrinsic urge to improve</i>	39	Thinking about changes
		32	Being open to improvement
		14	Results are important for Yourself
		10	Being well on your way
		6	Believing in improvement
Attitude (235)	<i>Limitations</i>	5	Awareness of the problem
		29	Not everything is possible
		5	Patients’ awareness because of the questionnaire

Behavior (436)	How to improve?	
		26 Discussing results in the professional team
		23 Evaluating what is going wrong
		15 Re-organizing care
		12 Always sit behind it
		10 Evaluating what is going well; Improving weaknesses
		8 Immediately dealing with the problem
		7 First changing simple things
	Measurement	10 Monitoring the progression
	Feedback	23 Concrete information
		22 Recognizable feedback
		16 Visual feedback
		14 Feedback report provides overview; Beautiful feedback report
		9 Not too much information
		7 Improvement scores are meaningful
		6 Prioritizing
		6 Providing examples for care improvement
		5 Explanation in feedback report; Classification tables ignore nuances; Numbers are less important
	Patients' input	14 Remarks patients are useful
		10 Remarks patients appeal to the professional
		5 Representative patient remarks
	Support with improvement plan	11 Visiting a clinic to discuss the feedback report
		6 Learning from each other
		5 Consultation between clinics; Interactive session
	Barriers	15 Lack of time
		8 Pressure
		6 Change of regime
		5 Financial support
	Facilitators	16 Committed team
		9 Own efforts lead to more patient-centred care

PC-care = Patient-centred care
Only codes presented with a frequency of 5 or more.

Discussion

Our study showed that merely providing auditing and feedback to professionals in fertility care about their performance on patient-centredness may not be sufficient to increase the level of this important dimension of quality of care. Even those clinics who initiated improvement plans based on the feedback report did not show statistically significant differences on their PCQ-Infertility scores. This might imply that auditing and feedback alone are not enough and that clinics need a more advanced improvement strategy.

From the qualitative part of this study, we were able to collect information to assist in the design of such a strategy. Interviews with different professionals identified that they are aware of what patient-centred care is, and they provided many suggestions on how to improve it. However, two steps of Hibbard's model were not met by the professionals and can therefore be considered as key factors toward optimizing the design of improving patient-centred fertility care.³¹ First, the professionals' knowledge about their actual provision of patient-centred care seems suboptimal. Second, progress can be made with professionals' desire to change toward more patient-centred fertility care.

To gain more insight into how to improve these two steps or key factors, we should explore the items that the professionals cited within the qualitative research. Professionals declared that they evaluated their performance regarding patient-centredness inadequately. This finding is in line with the study of Aarts *et al.*¹⁷ that found that health-care professionals' perceptions of their patients' experiences with fertility care were not in line with the patients' actual experiences. Also, studies in other health-care areas have reported similar results.^{32,33} To account for this inadequacy in professionals' perceptions, feedback must be more detailed, concrete, and clear to lead to increased knowledge about how care delivery is actually organized and performed.

Another item mentioned by the professionals concerned interclinic differences. All professionals underlined the necessity of a high standard of patient-centredness throughout the country, but this standard appeared to be different among the clinics. For example, large university clinics devoted a lot of attention to the dimension Continuity of Care. By contrast, smaller clinics that have only a few gynaecologists wished to focus on aspects such as Information Provision or Emotional Support. To account for these interclinic differences, feedback should be tailored to each clinic individually and be provided to all professionals involved in the fertility patients' care network. This is especially important when improving patient-centredness of care, which requires a more holistic, personalized approach that involves more than one physician.^{17,34-36}

The second factor that should be met to achieve improvement of patient-centred care is the motivation to change. Professionals mentioned they want to become the best clinic of the country, but when we opened the “black box” between T0 and T1³⁷ it became clear that only five clinics had undertaken any action toward improvement. We found this remarkable, as there is a growing recognition of patient-centredness as one of the core dimensions of quality of care.¹⁻³ Apparently, recognition does not result in a sufficient desire to improve the clinic’s level of patient-centredness. The professionals in our study mentioned that publically publishing the study’s results would help them in this process. This can be underlined by an example from Dutch fertility care: variation between clinics declined obviously after Dutch pregnancy rates per clinic were publically published.³⁸ Thus, publishing the clinics’ levels of patient-centredness could be a next step toward realizing competition between clinics, increasing the professionals’ urge to change and improve.

After exploring two of the key factors toward achieving care improvement (i.e., knowledge and motivation), some other statements from the qualitative research deserve additional attention. First, professionals stated they need help in formulating a concrete action and improvement plan. Subsequently, they prefer one person to be responsible for the execution and prolongation of the plan to achieve care improvement. Professionals also mentioned the importance of being audited more frequently (e.g., every year) as this re-stimulates the professional team to evaluate what has been improved and to redefine the improvement plan if necessary.³⁹ This notion on how to improve care corresponds with the complexity of implementing new procedures, which requires a substantial commitment of the professional team and sustained focus.³⁹⁻⁴⁰ Being part of a dedicated team^{41,42} and having a strong, allied health-care network of professionals can facilitate improvement projects being implemented as customary care.⁴³

A key strength of this study is the mixed-method design, which enabled us to both measure and understand the effect of auditing and feedback in one study. This provided us a more comprehensive picture of the difficulties and possibilities in light of improvements to patient-centred fertility care.^{22,23,44,45} Furthermore, the main outcome measure of the quantitative part was determined by a validated questionnaire, asking about patients’ experiences with care instead of the more subjective outcome measure of “patient satisfaction”.^{15,46,47} By involving different professions in the qualitative part of the present study, the recommendations are based on more than the gynaecologists’ opinions. The opinions of fertility care nurses, who are important members of the patients’ care network¹⁷, and the quality officers, who have more (factual) knowledge about quality improvement processes in general, were included in this study.

Some limitations about this study need to be addressed. First, because the effect of auditing and feedback was determined after a period of two years, it was difficult to distinguish between the possible effect of our intervention (i.e., auditing and feedback) and the possible effect of time. By asking the clinics what changes they made based on the feedback report specifically, we tried to approach the effect of the intervention alone. Second, response rates differed between T0 and T1 (76% and 57%, respectively). Nevertheless, we considered both response rates as sufficient to ensure the representativeness of the Dutch population experiencing infertility.⁴⁸ Third, we cannot exclude the possibility that only the professionals who are more motivated to improve patient-centred care agreed to take part in this study; our results may be partly influenced by selection bias. Fourth, we excluded all pregnant couples from our study; because they were a large proportion of our study population, this might have biased our results. However, we expected a confounding issue of strong association between patients' experiences with care and treatment outcome^{15,16}, so we decided that it would be most optimal for our purposes to exclude those patients.

The results of this mixed-method study can contribute to the improvement of patient-centred fertility care, as it has been shown that auditing and feedback alone are not sufficient. Of the four steps necessary to achieve improvement, *awareness*, the first step, seems to be adequately met within the fertility care community. The second step, increasing professionals' *knowledge* about the way they provide patient-centred care and translating that feedback into an actual improvement plan, is a challenging goal. Based on our study, we recommend providing fertility care professionals with detailed, concrete, individualized feedback on their performance. The third step, *attitude*, can be improved by increasing the professionals' motivation to change—for example, by publically publishing study results about patient-centred fertility care. Subsequently, to take the final step for care improvement, changing *behaviour*, the results must be discussed within the professional team to define the improvement goals and develop a clear action plan. To achieve sustainability with improvement goals, the execution of the action plan must receive follow up, and the possible effects should be re-measured. By implementing these aspects, the improvement of patient-centred fertility care is just one step ahead of us.

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"WE WILL GET YOU PREGNANT, LADY!" THESE WERE LITERALLY THE WORDS OF THE DOCTOR WHO WOULD MAKE SURE THAT I GOT WHAT I WANTED: A BABY. OF COURSE, I KNEW THAT THE CHANCE TO ACHIEVE PREGNANCY WAS FAR FROM GUARANTEED, BUT IT USED TO SOUND LIKE: "PLEASE, DO NOT THINK TOO MUCH ABOUT IT. YOUR GYNÁECOLOGY WILL MAKE SURE THAT IT WILL ALL TURN OUT WELL." BUT NO, THIS WAS DEFINITELY NOT WHAT I EXPECTED FROM A PATIENT-CENTRED CARE? I CAN ANSWER THIS QUESTION WITH A CATEGORICAL NO. MY HUSBAND AND I EXPERIENCED DURING THE FIVE YEARS THAT WE WERE WAITING FOR A NEW APPOINTMENT WITHIN TWO WEEKS TO START UP A NEW TREATMENT. AFTER I HAD UNDERGONE A LAPAROSCOPY TO FIGURE OUT WHY I WASN'T GETTING PREGNANT, THE DOCTOR SURPRISINGLY ANSWERED: 'THIS MUST BE A MISTAKE, BECAUSE IT WASN'T SUPPOSED TO BE THIS WAY AFTER SURGERY. OBVIOUSLY, YOUR BODY NEEDS MORE TIME TO RECOVER.' BUT BEFORE I COULD LEAVE, MY COLLEAGUE, AGAIN, SHE ONLY CONFIRMED WHAT HER COLLEAGUE HAD SAID. I HAD TO RETURN WITHIN TWO WEEKS TO CONTINUE MY TREATMENT (AND I HAD TO TALK TO THE SECRETARIES, WHO WERE ALSO FIRM IN THEIR STATEMENTS. I COULD NOT GET A NEW APPOINTMENT WITHIN TWO WEEKS TO CONTINUE MY TREATMENT. I WAS NO PROBLEM TO SEE THE DOCTOR AND THERE WAS NOTHING WRONG WITH MY BODY. I WAS VERY INSECURE AND HAD STRESSED ME OUT, WHICH OBVIOUSLY OFTEN HAD TO SIT NEXT TO PATIENTS WHO WERE ALREADY PREGNANT AND WERE TALKING ABOUT THE PROGRESS OF THEIR PREGNANCIES TOGETHER. THAT'S GOOD FOR INFERTILITY. IT WAS VERY HARD FOR ME TO SEE ALL THESE BIG BELLYS AND FEEL LIKE I WAS ASKED ME TO RETURN TO THE WAITING ROOM FOR A FEW MORE MONTHS. THERE I WAS, SITTING NEXT TO A MOTHER WITH A TWO-YEAR OLD CHILD. I WANTED TO PUT MYSELF IN HER SHOES AND FELT REALLY MISERABLE. BUT IT WAS NOT REALLY IMPRESSIVE. FOR EXAMPLE, IT HAPPENED SEVERAL TIMES THAT I HAD AN APPOINTMENT. OBVIOUSLY, THE DOCTOR WAS NOT AWARE OF THE FACT THAT I HAD READ MY MEDICAL RECORD BEFORE I ENTERED THE ROOM. ALSO, THE DOCTOR'S WORDS WERE CONTRADICTORY. IT SEEMED LIKE ALL DOCTORS HANDLED OUR CASES DIFFERENTLY. IT SCARED ME A LITTLE BIT, AS I ALREADY FELT PSYCHOLOGICAL PRESSURE FROM THE FACT THAT MY DOCTORS WERE ALL POINTING IN THE SAME DIRECTION. I FELT LIKE OUR OWN DOCTOR SHOULD NEVER HAVE INTRODUCED THE IVF TREATMENT OPTIONS. VERY CONFUSING, AS WE DID NOT KNOW WHAT A NEW TREATMENT I READ ABOUT IN A MAGAZINE. OUR DOCTOR HAD SAID THAT I WAS ELIGIBLE FOR THIS TREATMENT BEFORE. EVENTUALLY, I WAS THE ONLY ONE WHO WASN'T GETTING PREGNANT. MY HUSBAND AND I WERE WAITING FOR AN ULTRASOUND CHECK-UP. A LOT OF SMALL FOLLICLES WERE VISIBLE. THE DOCTOR SAID TO ME, BUT MY DOCTOR JUST SAID: 'IT LOOKS FINE, BUT THIS IS NOT WHAT YOU NEED OF COURSE!' WELL, I CAN SHARE, IS ABOUT MY ADMIS-

ALEIDA G. HUPPELSCHOTEN

NOORTJE T.L. VAN DUIJNHOF

ROSELLA P.M.G. HERMENS

CHRIS VERHAAK

JAN A.M. KREMER

WILLIANNE L.D.M. NELEN

LOSS DURING MY PREGNANCY. YES, WE FINALLY GOT PREGNANT AFTER 5 YEARS. THEREFORE, IT WAS EVEN MORE STRIKING WHEN THE DOCTOR ENTERED MY ROOM: 'IT IS VERY NICE AND QUIET ON THIS SECTION'. HE SAID: 'I AM COMING AND ASKED ME HOW I WAS DOING. I TOLD HIM I WAS 'ALLOWED' TO GO HOME, HE SAID. HE OBVIOUSLY THOUGHT THAT I HAD PREFERRED TO STAY ANOTHER DAY. A PERFECT EXAMPLE OF 'TALKING ABOUT THE PATIENT', INSTEAD OF

CHAPTER 8

IMPROVING PATIENT-CENTREDNESS OF FERTILITY CARE

USING A MULTIFACETED APPROACH:

STUDY PROTOCOL FOR A RANDOMIZED CONTROLLED TRIAL

Abstract

Background

Beside traditional outcomes of safety and (cost-)effectiveness, the Institute of Medicine states patient-centredness as an independent outcome indicator to evaluate the quality of healthcare. Providing patient-centred care is important because patients want to be heard for their ideas and concerns. Healthcare areas associated with high emotions and intensive treatment periods could especially benefit from patient-centred care. How care can become optimally improved in patient-centredness is unknown. Therefore, we will conduct a study in the context of Dutch fertility care to determine the effects of a multifaceted approach on patient-centredness, patients' quality of life (QoL) and levels of distress. Our aims are to investigate the effectiveness of a multifaceted approach and to identify determinants of a change in the level of patient-centredness, patients' QoL and distress levels. This paper presents the study protocol.

Methods/Design

In a cluster-randomized trial in 32 Dutch fertility clinics the effects of a multifaceted approach will be determined on the level of patient-centredness (Patient-centredness Questionnaire - Infertility), patients' QoL (FertiQoL) and levels of distress (SCREENIVF). The multifaceted approach includes audit and feedback, educational outreach visits and patient-mediated interventions. Potential determinants of a change in patient-centredness, patients' QoL and levels of distress will be collected by an addendum to the patients' questionnaire and a professionals' questionnaire. The latter includes the Organizational Culture Assessment Instrument about the clinic's culture as a possible determinant of an increase in patient-centred care.

Discussion

The study is expected to yield important new evidence about the effects of a multifaceted approach on levels of patient-centredness, patients' QoL and distress in fertility care. Furthermore, determinants associated with a change in these outcome measures will be studied. With knowledge of these results, patient-centred care and thus the quality of healthcare can be improved. Moreover, the results of this study could be useful for similar initiatives to improve the quality of care delivery. The results of this project are expected at the end of 2013.

Introduction

Would it not be great if every hospital worldwide provides consistent, high-quality medical care to all patients? Unfortunately, this is still not daily reality, which underlines the importance of research projects on the improvement of quality of care.¹ The Institute of Medicine structured the concept of 'quality of care' in 2001 by defining six aims around the core need for high-quality healthcare; 'safety', 'effectiveness', 'timeliness', 'efficiency', 'equity', and 'patient-centredness'.¹ Subsequently, quality measures were developed mainly focusing on safety and effectiveness, while patient-centredness was often neglected.¹⁻³ Patient-centredness is defined as 'care that is respectful of and responsive to individual patient preferences and needs and that is guided by patient values'.¹ Providing patient-centred care is important, because it can build caring relationships between patients and healthcare providers⁴⁻⁵, improve health outcomes^{4,6,7}, reduce costs^{4,6,8} and increase levels of patients' quality of life (QoL).⁹

Healthcare areas associated with high emotions and intensive treatment periods (for example, oncology or rheumatic care) could especially benefit from more patient-centred care. Fertility care is also one of these areas. In developed countries, infertility affects one in six couples who have tried to achieve pregnancy.^{10,11} About 55% of them seek medical help for their problem and start with a long lasting period of fertility workup and/or treatment¹². This period is a physical and psychological burden for the couples¹³. For example, a woman undergoing *in vitro* fertilization (IVF) treatment has to inject herself for several weeks to stimulate the production of oocytes, visit the clinic multiple times for ultrasound check-up and has to undergo transvaginal retrieval of oocytes. After fertilization of the oocytes in the laboratory with sperm, the resulting embryo is transferred to the uterus. Subsequently, the couple has to wait two weeks to find out whether pregnancy has occurred. If not, the couple can start a new IVF cycle. Eventually, this treatment period can take several months to even years, which underlines the impact of infertility and its treatment on patient's QoL. This may be seen in terms of impairments in psychosocial well-being, sexual satisfaction and marital relationship.¹³⁻¹⁶ Moreover, because of the high physical and emotional burden, about 23% of couples end treatment prematurely.¹⁷ Given these high percentage of patients deciding to terminate treatment early, frequently as a result of high psychological and psychical impact, every clinic should optimize its care towards more patient-centred care.^{13,14}

In Dutch fertility care, van Empel and colleagues showed that several parts of patient-centredness could be improved.¹⁸ How such improvement initiatives can be undertaken most successfully is still unknown. Moreover, there are potential barriers impeding improvement initiatives. For instance, professionals in fertility

care underestimate the importance of patient-centredness and have difficulties in estimating their performance correctly.¹⁹ Another barrier may be the organizational culture of a hospital. For instance, patients visiting hospitals that support teamwork are more satisfied with their care than patients visiting hospitals with other culture types (for example, hierarchical culture).²⁰⁻²³ Moreover, providing patient-centred care is often thought to be expensive and time consuming.^{24,25}

Obviously, steps need to be taken to achieve a behavioral change in professionals towards providing more patient-centred care. Because no magic bullets exist for changing healthcare providers' behavior²⁶, multiple interventions based on known barriers could accomplish this behavioral change and improve patient-centred care.

We designed a study to evaluate the effects of a quality improvement strategy consisting of three different elements; that is, a multifaceted approach. We hypothesize that providing clinicians with this multifaceted approach will improve the level of patient-centredness and thus healthcare quality. If so, this is essential in improving patients' QoL, reducing levels of distress and percentages of patients discontinuing treatment, and eventually reducing healthcare costs.

The main aim of this study is therefore to determine the effects of a multifaceted approach on patient-centredness, patients' QoL and levels of distress by: investigating the *effectiveness* of a multifaceted approach for care improvement on patient-centredness, patients' QoL and levels of distress; identifying *determinants*, at both patient and clinic levels, of an increase in the level of patient-centredness, an increase in patients' QoL and a decrease in distress levels; and performing a *process evaluation* to study the feasibility of the multifaceted approach and gain insight into factors that affected the impact of the intervention.

Methods / Design

Setting

In the Netherlands, secondary and tertiary fertility care is provided by three different types of clinics based on the kind of treatment they offer. Initial fertility assessment, ovulation induction and intra-uterine insemination are carried out in all Dutch clinics. The intermediate Dutch clinics can also start up and monitor the IVF and intra-cytoplasmic sperm injection treatments. However, oocytes retrieval and embryo transfer has to occur in one of the 13 licensed clinics (eight university hospitals, four general hospitals, and one private clinic). Almost all Dutch fertility clinics are national health service funded. Every Dutch citizen has a basic insurance coverage, which covers treatment and medication costs for

ovulation induction, intra-uterine insemination, and three cycles of IVF/intra-cytoplasmic sperm injection.

Study population

The study will be performed in a representative Dutch infertile patient group, under treatment in one of 32 Dutch clinics. All couples that participate in this study underwent at least one cycle of medically assisted reproduction (for example, ovulation induction, intra-uterine insemination, IVF, and intra-cytoplasmic sperm injection). Both women and their partners will be invited to participate in this study individually. However, because it is still unknown whether women and partner experiences with patient-centred fertility care are associated, only the women's data will be used to answer our main research questions. Partners' data will be used to analyze whether gender is a determinant of patient-centred fertility care. Those couples who are pregnant while completing the questionnaire set will be excluded from all analyses, because most questions about patient-centredness, patients' QoL and levels of distress are confounded in this patient group.^{18,27,28}

Ethical approval

The Regional Review Board for Research on Human Subjects (CMO) has received full ethical approval for this project (CMO No. 2011-034). The study is registered at clinicaltrials.gov NCT01481064.

Study design

In a cluster-randomized trial, the effects of a multifaceted approach on the level of patient-centred fertility care, patients' QoL and the level of distress will be identified. To include a representative patient group for baseline measurement, clinics will be asked to extract the address files of all patients who underwent medically assisted reproduction in their clinics during the past three months (2011) from their diagnosis treatment combination coding system. Per clinic, 25 to 75 patients will be randomly selected depending on the clinic's size. Participation is voluntary and anonymous. The couples will receive a letter with an invitation to participate. If they are willing, they complete an online questionnaire set, accessible by a personal code. Two weeks after the initial mailing, all patients will receive a reminder. Another three weeks later, non responders will receive a reminder with their personal codes and the additional option to complete a paper version of the questionnaire.²⁹

Following baseline measurement, all 32 participating clinics will be randomly assigned to usual care (16 clinics) or to the multifaceted approach (16 clinics) with

stratification for clinic size (large/medium/small) and IVF facilities (full licensed / intermediate / no IVF facilities). After one year of intervention exposure, all clinics again extract the address files of all patients who underwent medically assisted reproduction in the last three months for the after measurement. The same questionnaire set will be used, which again have to be completed by both the women and the partners separately. Figure 1 illustrates the study design schematically.

Questionnaires

The questionnaire set consists of three different questionnaires and some additional background questions for case-mix adjustment and to identify possible determinants of a change in the levels of patient-centredness, patients' QoL and distress levels.

Patient-centredness Questionnaire – Infertility

The Patient-centredness Questionnaire – Infertility, a validated instrument measuring patient-centredness of fertility care by asking about patients' experiences with care, is composed of 46 questions. This questionnaire contains seven subscales, namely: Accessibility, Information, Communication, Respect for patients' values, Continuity and transition, Patient involvement, and Competence.¹⁸ A higher score on the total Patient-centredness Questionnaire scale or one of the subscales represents a higher level of patient-centredness.

FertiQoL questionnaire

The internationally developed and validated FertiQoL questionnaire consists of two general items and two modules measuring QoL (the FertiQoL Core and the optional FertiQoL Treatment module). The Core module involves 22 fertility-specific items covering four subscales; Mind–Body, Emotional, Relational and Social. The optional treatment module assesses QoL related to the fertility treatment itself. In this study the Dutch version of the two general items and the FertiQoL Core module will be used. A higher score on the total FertiQoL scale or one of the subscales means better QoL.²⁷

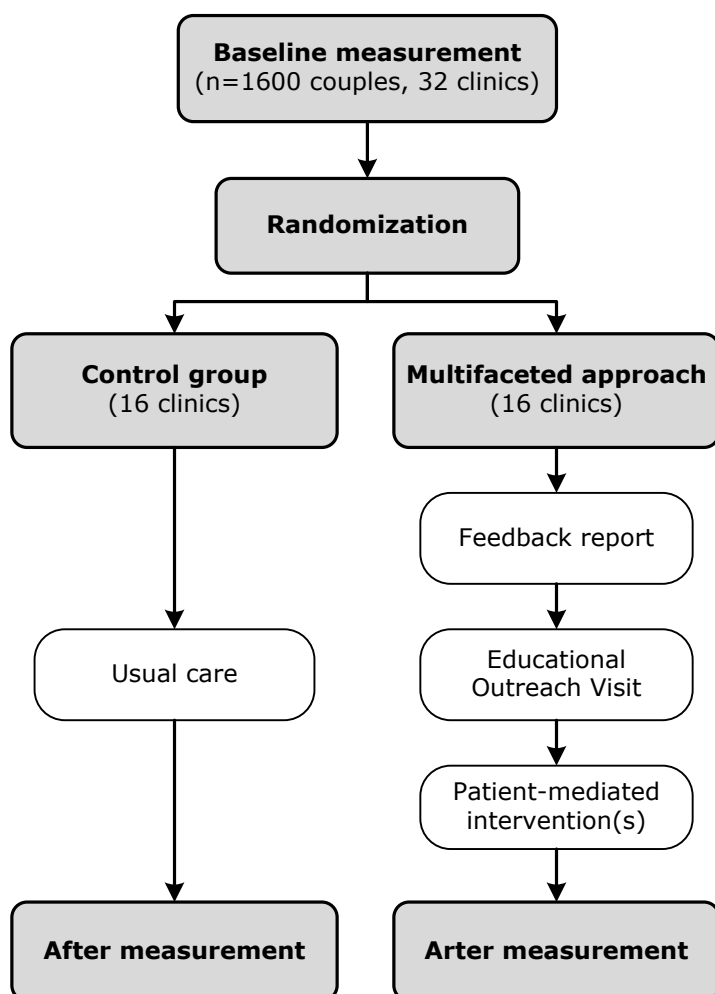
SCREENIVF questionnaire

The recently developed SCREENIVF questionnaire consists of 31 questions covering five emotional maladjustment scales (that is, five risk factors for increased emotional problems during fertility treatment); anxiety, depression, helplessness, acceptance regarding fertility problems, and perceived social support.³⁰ The assessments of anxiety, depression and perceived social support

are based on generic instruments (that is, Spielberger State and Trait Anxiety Inventory^{31,32}, Beck Depression Inventory³³, and Inventory of Social Involvement³⁴, respectively), and the assessments of helplessness and acceptance are based on a fertility specific instrument (that is, Illness Cognition Questionnaire^{35,36}). Subscale scores will be calculated according to the cutoff values described by Verhaak and colleagues.³⁰ Based on these five subscales, total SCREENIVF scores range from 0 to 5, indicating how many risk factors for increased emotional problems during fertility treatment are present.³⁰

Figure 1

Design of the study



The intervention

Clinics randomized for the multifaceted approach will be exposed to this intervention for one year. The content of the multifaceted approach is based on previous interviews with Dutch gynaecologists, fertility nurses and hospitals' quality officers about their potential barriers and facilitators for quality improvement, and on previous studies on patient-centred fertility care.^{19,37,38} These studies reported a large variation between clinics and the need for feedback about current performance for the clinicians involved.^{18,19} However, it is shown that audit and feedback alone is not enough; the effectiveness increases if feedback is detailed, offered in high intensity, with professionals' involvement and as part of a multifaceted intervention.³⁹⁻⁴² We therefore designed a multifaceted approach consisting of three elements: audit and feedback, educational outreach visits (EOVs), and patient-mediated interventions.

The feedback consists of a personalized paper report with the clinic's own results, benchmarked and presented in relation to all 32 participating clinics. To identify aspects of care with priority for improvement, quality improvement scores will be calculated per clinic and presented in the feedback report. The higher a quality improvement score ($3 - \text{perceived experience score} \times \text{importance score from the patients' perspective}$), the more need there is for improvement.¹⁸ The clinics receive this report shortly after baseline measurement and one month before the EOv will take place. Prior to this visit, the researcher and representative gynaecologist will discuss the results from the baseline measurement and define the most important items for EOv.

During EOv, the feedback reports will be discussed with the team of each clinic exclusively paying special attention to their high quality improvement scores. The EOvs are led by a researcher involved in baseline measurement and drafting the feedback reports. For the EOv, all members of the fertility team (gynaecologists, residents, nurses, secretaries, embryologists, analysts) will be invited. Each EOv results in the definition of improvement goals and a clear action plan with allocation of tasks defined by the professional team. The EOvs will also be attended by a quality officer of the hospital involved, who will manage the execution of the formulated action plan. Additionally, a representative of the Dutch Patients' Association of Infertility '*Freya*' who is a former patient of that clinic will be present. These representatives can present the needs and wishes of infertile patients during the EOv. All patients' representatives will receive a manual about EOvs and undergo a short training program for fulfilling their role in the EOv.

Finally, to enable clinics to translate items mentioned in the feedback report to the clinic's daily reality they are offered several patient-mediated interventions. For example, clinics can decide to organize focus groups or create online communities to gain more specific and detailed information from their patients about the care aspects with the highest quality improvement scores.

Following the EOV, the hospital's professional team and quality officer will be mainly responsible for the execution of the action plan. However, the researchers will monitor this process carefully by contacting the team every two months. Additionally, all professionals and representatives of *Freya* are invited to participate in an online study community. This community will be a platform for professionals to exchange their ideas about quality improvement programs. Besides, the researcher will write a blog at least every two months in which the quality improvement progress of all participating clinics will be described. The ideas and progress of one clinic can stimulate another clinic to improve even more.

Determinants of change in patient-centredness, patients' QoL and distress levels

Patient characteristics

The following patient characteristics will be collected, based on general and fertility literature as possibly being associated with patient-centred care, QoL and/or levels of distress: gender, age, ethnicity, level of education, duration of relationship, economic status, duration and cause of infertility, fertility treatments so far received, consumption of professional emotional support during fertility treatment, medical history, and recently experienced lifetime events (for example, death of a relative, being fired from work).^{18,43-46}

Clinic characteristics

Potential determinants at the clinic level will be collected by a professionals' questionnaire during patients' baseline measurement and by separate data collection during the EOV. The questionnaire will be spread electronically among all healthcare professionals (for example, gynaecologists, residents, nurses, laboratory employees, secretaries, and so forth) working at the fertility departments of the 32 participating hospitals. The questionnaire consists of two parts: twelve general questions about clinic characteristics (for example, number of fertility consultations per year, composition of the fertility team, mean age and sex ratio of the fertility team); and six questions from the Organizational Culture Assessment Instrument, a validated questionnaire to examine organizational culture based on the Competing Values Framework.⁴⁷⁻⁴⁹ The Competing Values

Framework recognizes that no hospital exhibits only one culture, but that multiple cultures and values coexist simultaneously⁵⁰ (that is, clan/family culture, adhocracy culture, market culture, and hierarchy culture). The four culture types relate to each other on a two-by-two matrix with two axes denoting both the flexibility and the orientation of the hospital to the outside world.^{47-49,51-53} In this study the validated Dutch version of the Organizational Culture Assessment Instrument will be used.⁵⁴

Additional possible determinants at the clinic level of a change in patient-centredness, patients' QoL and distress levels will be collected during the EOv. According to the literature, these characteristics may influence successful implementation of the action plan – such as, for example, the level of preparation before and the enthusiasm and agreement of the professional team during the EOv.⁵⁵ The researcher will record these team characteristics on a five-point Likert scale.

Sample size calculation

To account for a representative number of patients per clinic (that is, 25 to 75 patients per clinic) at least 1,600 couples will be included. The sample size calculation, which was based on the results of the previous Patient-centredness Questionnaire validation study¹⁸, confirmed that this number of patients is sufficient for a proper analysis. To detect a mean difference score of 0.25 between usual care and the multifaceted approach on patient centredness ($\alpha = 0.05$, two-sided testing, $\beta = 0.8$) at least 93 couples are required. Taking into account clustering of couples (30 couples/clinic) and a mean intracluster correlation coefficient of 0.13¹⁸, 1,023 couples have to be involved. With an expected response rate of 70%¹⁸, at least 1,462 couples have to be invited at both baseline and after measurement.

Data analysis

All data will be entered into a SPSS database (version 16.0 for Windows®; SPSS Inc., Chicago, IL, USA). Data analysis will be described following our two study aims.

Effectiveness of the multifaceted approach

To analyze the effectiveness of the multifaceted approach on patient-centredness, patients' QoL and levels of distress, the difference in baseline and after-measurement scores will be analyzed with adjustment for clustering of patients within clinics. Multilevel linear regression analyses will therefore be performed in which the intervention (multifaceted approach vs. usual care) will act as the

independent variable. The Patient-centredness Questionnaire – Infertility total and subscale scores, the FertiQoL total scores and the SCREENIVF scores will be used as dependent variables. Differences at baseline will be corrected for by taking baseline scores as a covariate in the final multilevel models.

Determinants of change in patient-centredness, patients' QoL and distress levels

First, all independent variables concerning baseline patient and clinic characteristics will be checked for collinearity. These variables include all patient and clinic background characteristics, as well as the four variables concerning hospital culture, and the team characteristics collected during EOv.

If a correlation coefficient >0.6 is found between two variables, preference will be given to the variable theoretically closest to actual outpatient performance. Subsequently, all independent variables will be tested in a univariate analysis with the dependent variables concerning the differences between patient-centredness, patients' QoL and levels of distress in baseline and after measurement. The variables tend to be associated and show enough interclinic variation will be included in three multilevel linear regression models to explain differences in an increase in patient-centredness, an increase in patients' QoL and a decrease in levels of distress, respectively. To assess which part of the variation can be explained by the determinants, the explained variance (R^2) per model will be calculated. Significance for all analyses will be set at $P < 0.05$.

Process evaluation

A process evaluation, according to Hulscher and colleagues⁵⁶, will be performed during and after the intervention to investigate the feasibility of the action plan formulated during the EOv. This evaluation will also make clear whether and to what extent professionals and patients used and appreciated the elements of the multifaceted approach. Especially, process evaluation is essential to find out how and to what extent clinics accomplished the third part of the multifaceted approach; that is, patient-mediated interventions.

During the intervention, telephonic interviews with the representative gynaecologists every two months will provide us with this information. Process evaluations at the end of the study will be based on a professional questionnaire, a questionnaire for the patients' representatives, and an addendum to the patients' questionnaire in the after measurement.

Discussion

The study is expected to yield important new evidence about the effects of a multifaceted

approach on the improvement of patient-centredness, patients' QoL and levels of distress in fertility care. Determinants at patient and clinic levels of a change in these variables will also be assessed. By having knowledge of these results, patient-centred care and thus quality of healthcare can be improved. This may lead to a higher patients' QoL, lower levels of distress in infertile couples, a reduction in patient discontinuing treatment prematurely and a reduction in healthcare costs.

To the best of our knowledge, this is the first study examining the effects of a multifaceted approach on patient-centred fertility care. In Dutch intensive care, a randomized trial is ongoing to determine the effect of a multifaceted approach on patient outcome and organizational process measures of care.⁵⁷ Completed studies examining the effects of a multifaceted approach on guideline implementation showed incompatible results.^{26,42,58} In a systematic review on this subject the effects of different elements of a multifaceted approach were described, showing that the EOv is one of the most common evaluated interventions, resulting in modest improvements (6%, range -4 to 17.4%) in process of care.⁴⁰ Audit and feedback and patient-directed interventions appeared to result in modest (7.0%, range 1.3 to 16.0%) and moderate (20.8%, range 10.0 to 25.4%) effects, respectively.⁴⁰ Lewin and colleagues evaluated the effects of different interventions to promote patient-centred care.⁹ Significant effects on patient satisfaction were demonstrated when using multifaceted approaches instead of usual care [59,60]. The majority of these studies were undertaken in the area of primary care. In fertility care, no overall sustainable effect of a multifaceted approach was found over audit and feedback on the level of guideline implementation.³⁷ This is in line with other studies on audit and feedback.³⁹

In sum, studies examining the effects of a multifaceted approach generally show slight improvements on patients' well-being and patient-centred care. However, no clear evidence is available regarding how many and what combination of interventions provides the highest improvement in quality of care. One of the strengths of our study is that we will use a multifaceted approach consisting of three different interventions, which has been shown to be effective in different studies³⁹ and is based on known professional barriers.^{19,37,38} Further, our outcome measures will be determined by validated and internationally developed questionnaires enhancing our study results. Finally, because one-third of all Dutch hospitals from all regions in our country will be approached for participation, representativeness

of Dutch infertile couples can be ensured. Owing to these strong elements of our study, our results provide more evidence about the effectiveness of a multifaceted approach on patient-centredness, patients' QoL and levels of distress in fertility care.

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"WE WILL GET YOU PREGNANT, LADY!" THESE WERE LITERALLY THE WORDS OF THE DOCTOR WHO WOULD MAKE SURE THAT I GOT WHAT I WANTED: A BABY. OF COURSE, I KNEW THAT THE CHANCE TO ACHIEVE PREGNANCY WAS FAR FROM GUARANTEED, BUT IT USED TO SOUND LIKE: "PLEASE, DO NOT THINK TOO MUCH ABOUT IT. YOUR GYNÁECOLOGY WILL MAKE SURE THAT IT WILL ALL TURN OUT WELL IN THE END." NO, THIS WAS DEFINITELY NOT WHAT I EXPECTED FROM A PATIENT-CENTRED CARE? I CAN ANSWER THIS QUESTION WITH A CATEGORICAL NO. MY HUSBAND AND I EXPERIENCED DURING THE FIVE YEARS THAT WE WERE WAITING FOR A NEW APPOINTMENT WITHIN TWO WEEKS TO START UP A NEW TREATMENT. SURPRISINGLY ANSWERED: 'THIS MUST BE A MISTAKE, BECAUSE IT WAS REALLY WHAT THE DOCTOR HAD TOLD ME. BUT BEFORE I COULD RETURN WITHIN TWO WEEKS TO CONTINUE MY TREATMENT (AND I HAD TO ASK THE SECRETARIES, WHO WERE ALSO FIRM IN THEIR STATEMENTS. I COULD NOT SEE THE DOCTOR AND THERE WAS NOTHING VERY INSECURE AND HAD STRESSED ME OUT, WHICH OBVIOUSLY OFTEN HAD TO SIT NEXT TO PATIENTS WHO WERE ALREADY PREGNANT AND WERE TALKING ABOUT THE PROGRESS OF THEIR PREGNANCIES TOGETHER. THAT'S GOOD FOR INFERTILITY. IT WAS VERY HARD FOR ME TO SEE ALL THESE BIG BELLYS IN THE WAITING ROOM. I ASKED ME TO RETURN TO THE WAITING ROOM FOR A FEW MORE MONTHS. THERE I WAS, SITTING NEXT TO A MOTHER WITH A TWO-YEAR OLD CHILD. I WANTED TO PUT MYSELF IN HER SHOES AND FELT REALLY MISERABLE. BUT IT WAS NOT REALLY IMPRESSIVE. FOR EXAMPLE, IT HAPPENED SEVERAL TIMES THAT I HAD AN APPOINTMENT. OBVIOUSLY, THE DOCTOR WAS NOT AWARE OF THE FACT THAT HE HAD READ MY MEDICAL RECORD BEFORE I ENTERED THE ROOM. ALSO, THE INFORMATION WAS CONTRADICTORY. IT SEEMED LIKE ALL DOCTORS HANDLED OUR CASE DIFFERENTLY. IT SCARED ME A LITTLE BIT, AS I ALREADY FELT PSYCHOLOGICAL PRESSURE. THAT MY DOCTORS WERE ALL POINTING IN THE SAME DIRECTION. I FELT THAT OUR OWN DOCTOR SHOULD NEVER HAVE INTRODUCED THE IVF TREATMENT OPTIONS. VERY CONFUSING, AS WE DID NOT KNOW WHAT A NEW TREATMENT I READ ABOUT IN A MAGAZINE. OUR DOCTOR HAD TOLD US THAT OUR HOSPITAL, WHILE EXACTLY THE OPPOSITE WAS TRUE ACCORDING TO THE CRITERIA ELIGIBLE FOR THIS TREATMENT BEFORE. EVENTUALLY, I WAS TOLD THAT I WAS BEING RECOMMENDED FOR COMMUNICATION, MY HUSBAND AND I WERE GOING FOR AN ULTRASOUND CHECK-UP. A LOT OF SMALL FOLLICLES WERE VISIBLE. THE DOCTOR TOLD ME, BUT MY DOCTOR JUST TOLD ME THAT I LOOKS FINE, BUT THIS IS NOT WHAT YOU NEED OF COURSE!' WELL, I WOULD LIKE TO SHARE, IS ABOUT MY ADMIS- SION TO THE HOSPITAL DURING MY PREGNANCY. YES, WE FINALLY GOT PREGNANT AFTER A LONG TIME. THEREFORE, IT WAS EVEN MORE STRIKING THAT THE DOCTOR ENTERED MY ROOM: 'IT IS VERY NICE AND QUIET ON THIS SECTION' HE SAID. HE OBVIOUSLY THOUGHT THAT I WOULD HAVE PREFERRED TO STAY ANOTHER DAY. A PERFECT EXAMPLE OF 'TALKING ABOUT THE PATIENT', INSTEAD OF

ALEIDA G. HUPPELSCHOTEN

WILLIANNE L.D.M. NELEN

GERT P. WESTERT

RON J.T. VAN GOLDE

EDDY M.M. ADANG

JAN A.M. KREMER

CHAPTER 9

IMPROVING PATIENT-CENTREDNESS BY A MULTI-FACETED

INTERVENTION WITH FEEDBACK AND EDUCATION BY

PATIENTS:

A CLUSTER-RANDOMIZED TRIAL IN FERTILITY CARE

SUBMITTED VIA

Abstract

Background

In recent years, it has become clear that healthcare should become more patient-centred. However, an effective improvement strategy for patient-centred care, including the wishes and preferences of patients and tackling the barriers that professionals experience in daily clinical care, has not been found yet. Our main aim was to examine the effect of a multifaceted intervention on the improvement of patient-centredness in fertility care.

Methods

We performed a cluster randomized controlled trial within 32 Dutch fertility clinics. A total of 1620 infertile women, under fertility treatment in one of the participating clinics, were randomly selected for participation during baseline measurement. They received the validated Patient-Centredness Questionnaire-Infertility (PCQ-Infertility) to measure their clinics' levels of patient-centredness. A multifaceted intervention strategy, consisting of audit and feedback, educational outreach visits, and patient-mediated interventions, was executed for one year in the intervention group, consisting of 16 clinics. The remaining 16 clinics performed care as usual. For the after measurement, we used the same PCQ-Infertility questionnaire among 1565 infertile women to measure clinics' levels of patient-centredness again.

Results

A total of 696 patients (response 58.4%) were eligible for analysis at baseline measurement. At the after measurement, we analysed the data of 730 patients (response 60.4%). No significant differences in case-mix adjusted PCQ-Infertility total scores were found between the intervention and control group at after measurement. However, scores on the continuity of care subscale were significantly higher in the intervention group compared to the control group ($B=0.20$; 95% $CI=0.00-0.40$; $p\text{-value}=0.047$). Moreover, patients in the intervention group had significantly better experiences with fertility care than patients in the control group when they were younger than 36 years, when they began their fertility treatment after our study had started, and when they also used complementary and alternative medicine ($B=0.31$; 95% $CI=0.14-0.48$; $p\text{-value}<0.001$).

Conclusions

A multifaceted intervention including feedback and education was not sufficient to improve patient-centredness. An increase in the level of patient-centred care could however been achieved in specific patient groups. These results are stimulating and can guide future research in which we should focus even more on individualized strategies and outcome measures.

Introduction

"Patient-centredness is not the route to a point, it is the point". With this statement, Don Berwick emphasizes the importance of providing care that is adjusted to patients' preferences, needs and values.^{1,2} Patient-centredness is a contemporary theme given the rising number of publications on this subject.³⁻⁷ There are several reasons why healthcare should become more patient-centred. First, because it is 'just the right thing to do', reflecting the ethical norms inherent in medicine.⁸ Also the demonstrated associations between patient-centred care and improved clinical outcomes^{9,10}, decreased healthcare costs^{11,12}, and more satisfaction among patients and healthcare workers¹³⁻¹⁵ are motivators for professionals to improve their clinics' levels of patient-centred care.

Previous studies have shown that the level of patient-centredness in current healthcare is not optimal yet.^{7,16,17} Apparently improvement needs more than professionals' good intentions and could benefit from consistent and well-performed improvement projects.¹⁸ An effective improvement strategy for patient-centred care should include the wishes and preferences of patients and tackle the barriers that professionals experience in providing patient-centred care.^{3,4,7} Known barriers from the literature are, for example, a lack of professional urge to change their performance or difficulty to translate feedback into a concrete improvement design.^{3,19-23} Also a lack of time and monetary resources are brought forward by professionals as important reasons hampering the improvement of their clinics' levels of patient-centredness.^{19,20} So far, the most optimal improvement strategy to overcome these barriers and really improve patients' experiences with patient-centred care has not been found yet. Moreover, patient-centredness has shown to be associated with several patient characteristics, such as age and education.²⁴⁻²⁶ However, the effect of these characteristics on an improvement strategy for patient-centred care has not been studied yet.

Therefore, the main aim of our study was to determine the effect of a multifaceted approach, consisting of three elements, on the improvement of patient-centred care. Next, we identified determinants at the patient level of the effect of our intervention. Finally, we calculated the costs of the multifaceted approach from a societal perspective. We performed our study in the area of fertility care, as it is known that infertile patients suffer from a high physical and physiological burden during treatment and could especially benefit from patient-centred care.²⁷

Methods

Study design

We performed a cluster randomized controlled trial in 32 Dutch fertility clinics to determine the effect of a multifaceted approach on the level of patient-centred fertility care. After randomisation, 16 clinics were exposed to the intervention for one year and the other 16 clinics performed care as usual. The institutional ethics committee of Radboud University Medical Centre, Nijmegen provided ethical approval for this research to proceed (CMO nr 2011/034). Our trial was registered with ClinicalTrials.gov (NCT01481064) and we reported our results according to the CONSORT statement for cluster randomized trials. An extensive description of the design of our study is published elsewhere.²⁸

Randomization

We used fertility clinics instead of patients as the unit of randomization to avoid contamination of the intervention. For randomization, clinics were stratified according to the clinic size (large, medium and small) and subsequently assigned to either the control group or multifaceted strategy. Three research associates performed the blinded randomization procedure by drawing randomly numbered and sealed envelopes.

Setting and study population

In the Netherlands, fertility care is provided through three different types of fertility clinics. A total of 13 large clinics are licensed to perform all kinds of Medically Assisted Reproduction (MAR). The intermediate clinics have to refer their patients to these larger clinics for the laboratory phase and embryo transfers of the *in vitro* fertilization (IVF) and intracytoplasmic sperm injection (ICSI) treatments. The small fertility clinics only perform fertility assessment, ovulation induction (OI) and intra-uterine inseminations (IUI). In addition, a few very specialized fertility treatments are centralised within only one or two Dutch fertility clinics (e.g. Testicular Sperm Extraction (TESE) and Preimplantation Genetic Diagnosis (PGD)). For our study, we included patients who underwent at least one cycle of MAR in a small, intermediate or large Dutch fertility clinic. To do so, we asked clinics to extract the names and addresses of all patients who underwent MAR in their clinic in the past three months (i.e. summer 2011 and winter 2012) from their Dutch coding system for diagnosis and treatment. Subsequently, we randomly selected 25 to 75 patients per clinic, depending on the clinic size. We invited only the women of the infertile couples to participate as previous research has shown that women and their partners have comparable results on the primary outcome measure, i.e. patient-centredness of care.²⁹ Because a strong

association between fertility treatment outcome (i.e. pregnancy) and our main outcome measure (i.e. patient-centredness of care) was previously shown³⁰, we excluded all patients who had achieved pregnancy during the study period to avoid bias of our study results.

Sample size

Our sample size calculation was based on a previous Dutch study using the same patient questionnaire to determine the level of patient-centred fertility care as we did.³⁰ The mean overall patient-centredness score in this study was 2.19 (SD 0.43), and ranged from 1.72 (SD 0.62) to 2.47 (SD 0.28) on a scale from 0 to 3. We considered an improvement of 0.25 points in our study as relevant. To detect this difference between usual care and the multifaceted approach (alpha=0.05, two-sided testing, beta=0.8) at least 93 couples were required. Taking into account clustering of couples (30 couples per clinic) and a mean intracluster-correlation coefficient of 0.13³⁰, 1023 couples had to be involved. With an expected response rate of 70%³⁰, at least 1462 couples had to be invited at both baseline and after measurement.

Intervention

The content of the intervention was based on the existing literature about effective improvement strategies in healthcare^{4,22,31-33} and on previous interviews with Dutch fertility care professionals about their vision on patient-centred fertility care and its improvement.²³ During one year, all 16 intervention clinics were exposed to the multifaceted approach, which consisted of three elements: 1) Audit and feedback, 2) Educational Outreach Visits, and 3) Patient-mediated interventions. The audit was performed by means of a patients' questionnaires, measuring clinics' levels of patient-centred care. The feedback consisted of a paper report with the clinic's own results regarding their level of patient-centred care. These results were benchmarked and presented in relation to all 32 participating clinics. To identify aspects of care with priority for improvement, quality improvement scores (QI score) were calculated per clinic, which were based on both the patients' importance of and experiences with different elements of patient-centred care, according to van Empel *et al.*³⁰ The higher a QI score the more need there was for improvement. Two weeks after the clinics received the feedback report, we performed an Educational Outreach Visit (EOV) in each of the 16 clinics. We discussed the content of the feedback report with the entire fertility care team, paying special attention to their highest QI scores. Per clinic, a former patient and a quality officer were invited to participate in these EOVs as well. Former patients were invited for their personal experiences regarding fertility care in this particular hospital and were recruited by the Dutch Patients'

Association of Infertility 'Freya'. Prior to the EOv, these patients received a manual and underwent a short training to prepare their role in the EOv most optimally. Quality officers were invited for their experiences with performing improvement strategies in general. The main goal of each EOv was to define improvement goals and a clear action plan with allocation of tasks. We aimed for the definition of really concrete action points, such as 'Provide all patients with a small card including the name of their main doctor and important phone numbers of the clinic', or 'At the end of each treatment phase, mention the possibility to visit a medical psychologist during consultation'. Furthermore, clinics were informed about different patient-mediated interventions to enhance the communication with their patients (e.g. organizing focus groups). Following the EOv, the fertility teams were mainly responsible for the execution of the action plans. However, the researcher monitored this process carefully and contacted the team every two months by phone to discuss the progress on the execution of their action plan. Moreover, we started an online community for the participating professionals and former patients to interchange their ideas and actions regarding the improvement of their care anonymously. Finally, clinics received an update on the progress of the study every two months by means of a newsletter, intended to stimulate clinics' willingness to improve.

Outcome measures

Patient-centredness of fertility care

To measure the level of patient-centredness in fertility care (i.e. our first study aim), we used the Patient-Centredness Questionnaire-Infertility (PCQ-Infertility). This is a validated instrument asking patients about their experiences with fertility care.³⁰ The PCQ-Infertility is composed of 46 questions and contains seven subscales, namely: Accessibility (2 items, e.g. 'Was it a problem for you to contact staff if you had any questions?'); Information (11 items, e.g. 'Did you receive an overview of your treatment plan with a time schedule?'); Communication (7 items, e.g. 'How often did your physician take you seriously?'); Respect for patients' values (7 items, e.g. 'How often did your physician show an interest in your personal situation?'); Continuity and transition (7 items, e.g. 'How often did you have an appointment with the same physician?'); Patient involvement (3 items, e.g. 'Was decision-making shared with you, if preferred?'); and Competence (6 items, e.g. 'How often was your physician well-prepared for an appointment?'). A higher score on the total PCQ scale or on one of the subscales (range 0-3) indicates a higher level of experienced patient-centredness.³⁰

Determinants of the effect of the multifaceted intervention

In an addendum to the PCQ-Infertility, we asked for patients' background characteristics to study their effect on the multifaceted approach. The selection of these characteristics was based on both general and fertility literature as possibly being related to patient-centred care, such as: age, ethnicity, level of education, duration and cause of infertility, consumption of professional emotional support during fertility treatment, and recently experienced life-time events (e.g. death of a relative, being fired from work).^{24,26,30,34,35} As a previous study showed a significant association between patient-centredness of fertility care and patients' psychosocial status³⁶, we also measured patients' levels of QoL and risk factors for emotional maladjustment using the FertiQoL and SCREENIVF questionnaires, respectively. We used the Dutch version of the FertiQoL Core module, existing of 24 fertility-specific items covering four subscales, i.e. Mind-Body, Emotional, Relational and Social. A higher score on the FertiQoL questionnaire (range 0-100) means better QoL.³⁷ The SCREENIVF questionnaire consisted of 31 questions covering five emotional maladjustment scales, namely: anxiety, depression, helplessness, acceptance regarding fertility problems, and perceived social support.³⁸ All five scales had individual cut-off values to determine whether a patient was at risk at this specific domain.³⁸ With a result above the cut-off value of at least one of these scales, a patient is considered at risk.³⁸

Costs

We evaluated the costs associated with the implementation and execution of the multifaceted approach from a societal perspective, including the intervention costs, costs for additional healthcare consumption and productivity losses. All costs were calculated within a time frame of one year, as we expected no additional effects of our intervention after one year. For the intervention costs, we included costs on the basis of actual exposure with the audit and feedback, EOVs and execution of the action plans. We calculated the total intervention costs, the intervention costs per clinic and the costs per patient per clinic by dividing the clinic costs by the total number of patients that were under treatment in 2011 in that specific clinic. Costs for audit and feedback included the costs for the development, printing and shipping of the questionnaires and feedback reports. EOv costs included the time of the researcher and fertility team members and a treat for the EOv participants. We determined the costs of the execution of the action plan and patient-mediated interventions by means of a personalized questionnaire to the 16 representative gynaecologists of the intervention clinics. Clinic changes having no clear costs or costs that were not accurately measurable were not taken into account (e.g. gynaecologists paying more attention to patients' emotions). Finally, researcher's time expenses for coordinating the clinics were included.

The costs for additional healthcare consumption included the medical costs for visiting other healthcare providers than gynaecologists, i.e. medical specialists, general doctors, physiotherapists, psychologists, dieticians, and physicians providing complementary and alternative medicine. For productivity losses, we measured the losses associated with patients' visits to the fertility clinics (i.e. travelling time, waiting time and time for the actual appointment). Also productivity losses due to sickness absence were taken into account. Data concerning the additional healthcare consumption and productivity losses were collected through an addendum to the patients' questionnaire. Subsequently, all prices were calculated from guidelines for cost related research in the Netherlands.³⁹

Data collection

For data collection, we composed an online patient questionnaire consisting of the PCQ-Infertility, the FertiQoL and SCREENIVF questionnaires and several background questions. During baseline and after measurement, all selected patients received an invitation by mail in which they were asked to complete the online questionnaire set. Two weeks later, a reminder was sent by mail. The non-responders received a paper version of the questionnaire three weeks later. At the after measurement, one gynaecologist per clinic (i.e. our contact) received a questionnaire per mail about the costs associated with the execution of the action plan and patient-mediated interventions. A reminder was sent after two weeks. Non-responders were contacted by phone as a final reminder.

Statistical analysis

We compared all patient characteristics between the control and intervention groups at both baseline and after measurement using t-tests for independent samples and chi-square tests when appropriate. We determined the effect of the multifaceted approach on the level of patient-centredness by comparing PCQ-Infertility total and subscale scores at the after measurement between the intervention and control group. Differences at baseline were corrected for by taking median baseline scores at the clinic level up as a covariate. Our analyses were performed with adjustment for clustering of patients within clinics and by taking into account relevant case-mix adjusters. Therefore, we performed multilevel multivariate regression analysis in which the PCQ-Infertility total and subscale scores acted as the dependent variables. The group variable (intervention vs. control), baseline scores and case-mix adjusters acted as the independent variables. To select relevant case-mix adjusters, we performed a series of univariate analyses with all background characteristics, including the results of the FertiQoL and SCREENIVF scores. Those associated with the PCQ-Infertility total score ($p < 0.20$) were selected as case-mix adjusters. In case of

collinearity (correlation analyses; Spearman's $\rho > 0.6$), we selected the clinically and theoretically most relevant characteristic. Finally, we excluded the statistically insignificant variables via manual backward elimination to come to our final model.

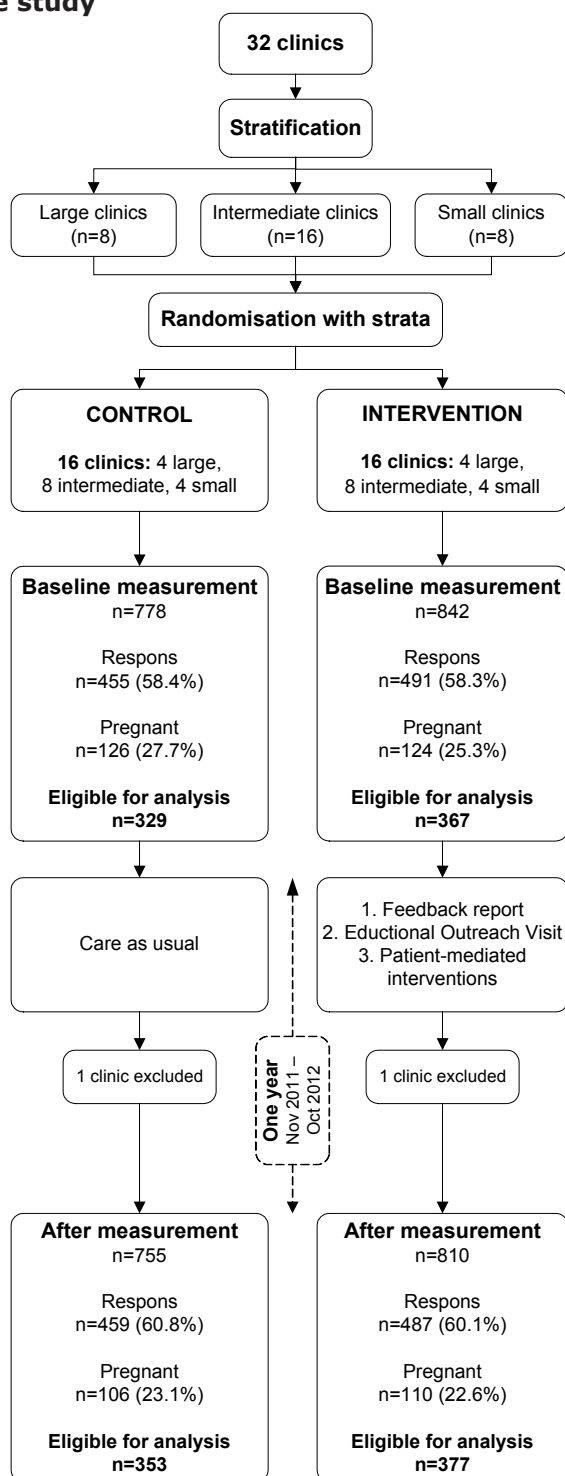
Subsequently, we included interaction terms to our previous model concerning the PCQ-Infertility total scores to come to determinants of the effect of the intervention. We first dichotomized all continuous background characteristics into clinically relevant categories for a clearer interpretation of the interaction terms. For example, we dichotomized the characteristic: 'Fertility care experience in months' into 'Already under treatment before the intervention started' (i.e. more than 12 months experience) and 'Under treatment after the intervention started' (i.e. 12 months experience or less). Then we created interaction terms for all background characteristics and the study group (intervention vs. control) and deleted the insignificant interaction terms through manual backward elimination.

Finally, to study a potential difference in costs for additional healthcare consumption and productivity losses between the control and intervention groups, we performed multilevel linear regression analyses after we had log-transformed the data because of a skewed distribution of the costs. Significance for the analyses was set at $P < 0.05$. Analyses were performed using SPSS (version 20.0 for Windows®, SPSS Inc., Chicago, IL, USA).

Results

At baseline measurement, a total of 1620 patients were invited to participate and 946 patients (response 58.4%) completed the questionnaire set. After excluding 250 pregnant patients, the results of 696 patients were taken up in the analysis. Shortly after baseline measurement, two intermediate fertility clinics merged to one new clinic. As it concerned one control clinic and one intervention clinic, we decided to exclude these clinics from our study to avoid extensive contamination of our intervention. After measurement was thus performed among 30 clinics and we invited a total of 1565 patients. The questionnaire set was completed by 946 patients (response rate 60.4%). After excluding 216 pregnant patients, 730 patients were eligible for our main analysis. Figure 1 shows the flowchart of this study.

Patients' background characteristics at baseline measurement were comparable between the control and intervention group ($p > 0.05$). Table 1 presents the patient characteristics at after measurement. Except for the scores on the FertiQoL and SCREENIVF questionnaires, no differences existed between the control and intervention group. Table 1 also shows which 14 background characteristics were selected as case-mix adjusters for our main analysis.

Figure 1.**Flowchart of the study**

The mean PCQ-Infertility total and subscale scores from baseline and after measurement are presented in table 2. This table also shows the results of the multilevel multivariate regression analysis (i.e. case-mix adjusted differences). At the after measurement, case-mix adjusted PCQ-Infertility total scores did not significantly differ between the intervention and control group ($B=0.06$; 95% CI= $-0.04-0.15$; $p\text{-value}=0.246$). However, on the PCQ-Infertility subscale 'Continuity of care', the case-mix adjusted scores were significantly higher in the intervention group compared to the control group ($B=0.20$; 95% CI= $0.00-0.40$; $p\text{-value}=0.047$). No significant differences were found on the remaining PCQ-Infertility subscales.

Table 3 shows the effect of the intervention on the PCQ-Infertility total scale after adding three significant interaction terms to the model. The effect of the intervention turned out to be significantly better when patients were younger than 36 years, when patients started their fertility treatment after the start of the intervention (i.e. fertility care experiences was 12 months or less) and when patients used complementary and alternative medicine (CAM). In cases patients met all three conditions, the scores in the intervention group were on average 0.31 points higher compared to the control group (95% CI= $0.14-0.48$; $p\text{-value}<0.001$).

Figure 2 provides an overview of the effect of the intervention for all different combinations of the three relevant background characteristics. In four of the eight possible scenarios (i.e. 35% of our entire patient group), the intervention group scored significantly better than the control group.

An overview of all costs is presented in table 4. Total intervention costs of the multifaceted approach were €64.628. Of these costs, €4.110 was due to the audit and feedback, €14.327 was spend on the educational outreach visits. The costs for the patient-mediated interventions and execution of the action points was €46.191. Median intervention costs per clinic per year were €3324 (range: €959 – €11.550). The median yearly costs per patient per clinic were €13, ranging from €2 to €28 and in general, these costs were lower for the larger IVF clinics and higher for the smaller clinics. Also the costs for additional healthcare consumption and productivity losses are presented in table 4. Multilevel linear regression analyses on log-transformed data showed no significant differences between the productivity losses in the intervention and the control group during after measurement.

Table 1**Patient characteristics at the after measurement and their association with the PCQ-Infertility total score in univariate analysis**

Background characteristics	Control (n=353)	Intervention (n=377)	Differences p-value	Univariate analysis B
Median age (years, range)	33.0 (22.0-44.0)	33.0 (23.0-43.0)	0.70	0.01 *
Level of education (low-middle / high, %)	50.6 / 49.4	45.7 / 54.3	0.19	0.08 *
Ethnic background (Dutch / non-Dutch, %)	84.4 / 15.6	83.0 / 17.0	0.61	0.10 *
Net monthly family income (≥ 1.5 x modal income, %)	82.7	79.9	0.46	0.04
Median duration of:				
- relationship (months, range)	9.0 (2.0-25.0)	9.0 (1.0-25.0)	0.48	0.00
- fertility care experiences (months, range)	17.0 (1.0-125.0)	18.0 (0.0-171.0)	0.43	0.00 *
Treatment type (non-ART / ART, %)	53.3 / 46.7	48.8 / 51.2	0.23	-0.21 *
Diagnosis (male / female / both / unexplained, %)	25.4 / 27.9 / 12.5 / 34.2	23.9 / 28.7 / 9.6 / 37.8	0.52	0.16 *
Experienced miscarriages or EUGs (%)	13.9	12.5	0.56	-0.01
Being childless(%)	73.6	72.7	0.78	-0.01
Clinic visits as a couple (%)	56.0	58.8	0.45	0.08 *
Median clinic visits per month (n, range)	4.0 (1.0-15.0)	4.0 (1.0-15.0)	0.91	-0.01 *
Median travel time to clinic (minutes, range)	20.0 (0.0-180.0)	20.0 (0.0-180.0)	0.15	0.00 *
Recently visited a general practitioner (%)	29.3	31.3	0.55	-0.06 *
Use of physiotherapy (%)	12.8	12.3	0.84	-0.08 *
Use of complementary and alternative medicine (%)	19.9	18.4	0.62	-0.15 *
Use of professional psychosocial support (%)	14.0	11.5	0.31	0.01
Medical history (%)	12.6	11.0	0.51	0.10 *
Lifetime events (%)	10.5	11.5	0.67	-0.04
Being unemployed (%)	10.8	13.6	0.25	0.02
Reported ill at work in past 3 months (%)	42.2	44.0	0.65	-0.03
Quality of life (median, range)	65.2 (30.2-94.8)	62.5 (11.5-95.8)	0.02	0.01 *
Risk factors for emotional problems (%)	56.1	66.0	0.01	-0.17 **

* This background characteristic were associated ($P < 0.20$) with the PCQ-Infertility total score and therefore selected as a potential case-mix adjuster.** The SCREENIVF scores were also associated to the PCQ-Infertility total scores, but due to collinearity with the FertiQoL scores (Spearman's $\rho = -0.71$), we excluded this variable from further analysis.

Table 2
Differences between intervention (I) and control (C) groups at baseline and after measurement

	Baseline measurement			After measurement			Difference Δ I-C	Case-mix adjusted differences ^a B (95% CI)
	C (n=329)		I (n=367)	C (n=353)		I (n=377)		
	Mean (SD)		Mean (SD)	Mean (SD)		Mean (SD)		
PCQ-total	2.15 (0.43)	2.17 (0.44)	2.17 (0.44)	2.17 (0.43)	2.23 (0.43)	2.23 (0.43)	0.06	0.06 (-0.04-0.15)
Accessibility	2.38 (0.75)	2.28 (0.79)		2.39 (0.78)	2.46 (0.68)		0.07	0.14 (-0.06-0.33)
Information provision	2.12 (0.58)	2.10 (0.62)		2.07 (0.62)	2.11 (0.63)		0.04	0.02 (-0.09-0.14)
Communication	2.49 (0.54)	2.49 (0.53)		2.51 (0.52)	2.53 (0.53)		0.02	0.05 (-0.06-0.15)
Respect of patients' values	1.85 (0.75)	1.90 (0.77)		1.89 (0.73)	1.95 (0.78)		0.06	0.07 (-0.10-0.23)
Continuity of care	1.74 (0.57)	1.90 (0.56)		1.77 (0.62)	2.00 (0.56)		0.23	0.20 (0.00-0.40)*
Patient involvement	2.28 (0.67)	2.24 (0.67)		2.30 (0.66)	2.31 (0.67)		0.01	0.05 (-0.09-0.19)
Staff's competence	2.41 (0.42)	2.45 (0.42)		2.46 (0.37)	2.48 (0.40)		0.02	0.02 (-0.07-0.10)

^a The case-mix adjusted differences are the result of the multilevel multivariate linear regression analyses with manual backward elimination of 14 relevant case-mix adjusters and baselines scores.
* Results in the intervention group were significantly higher (i.e. 0.20 points; p-value=0.047) on the Continuity of care subscale compared to the control group when adjusted for diagnosis, treatment type, CAM use, having a recent medical history, quality of life and PCQ-Infertility scores at baseline measurement.

Table 3

Case-mix adjusted difference between intervention and control group on the PCQ-Infertility total score when taking into account relevant interaction terms.

Characteristics	Differences in PCQ-Infertility total scores	
	B	(95% CI)
Intercept	0.18	(-0.41-0.76)
Intervention vs. Control	0.31	(0.14-0.48)^a
Lower level of education	0.06	(0.00-0.12)
Male vs. unknown diagnosis	0.11	(0.03-0.19)
ART treatment	0.14	(0.07-0.20)
Visits as a couple	0.09	(0.03-0.15)
Quality of life	0.01	(0.01-0.01)
Baseline measurement	0.62	(0.36-0.87)
CAM use	-0.18	(-0.28- -0.07)
Under treatment after intervention started	0.01	(-0.08-0.09)
Age < 36 years	-0.11	(-0.20- -0.03)
INTERACTION TERMS: Characteristic * Study group		
Under treatment after intervention started	-0.11	(-0.23-0.00)
Age < 36 years	-0.11	(-0.23-0.00)
CAM use	-0.17	(-0.31- -0.03)

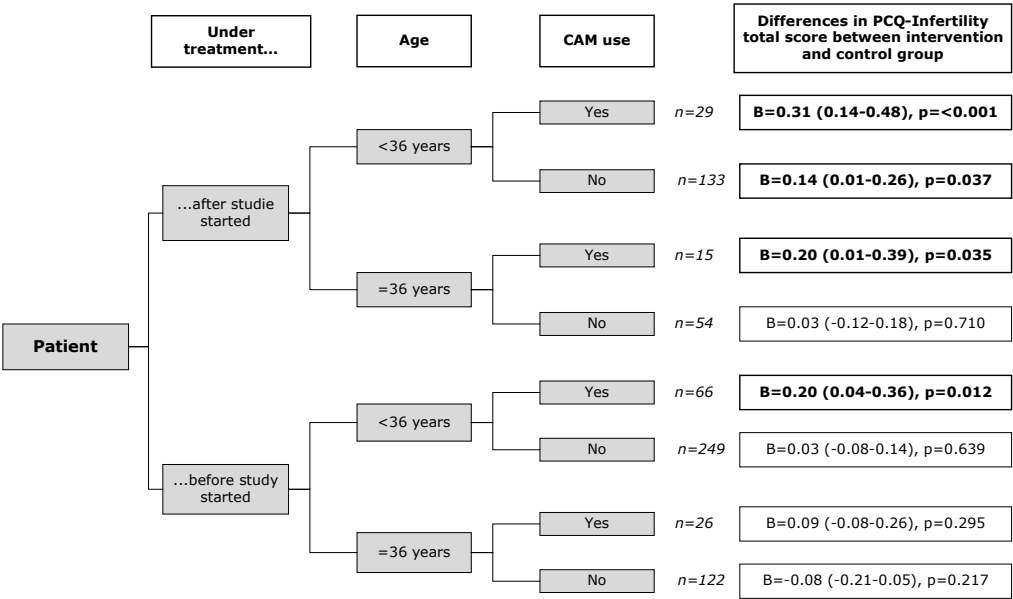
^a When adjusted for the nine presented patient characteristics, the intervention group had a 0.31 points (95% CI=0.14-0.48) higher score on the PCQ-Infertility total scale compared to the control group in case patients started treatment after the intervention had started, were younger than 36 years and used CAM.

Discussion

A multifaceted approach, consisting of audit and feedback, educational outreach visits and patient-mediated interventions, did not improve the entire level of patient-centred fertility care. However, we can still consider our results as an important step towards the improvement of patient-centred care, because patients' experiences did improve among three important patient sub groups. These results suggest that patient-centredness improvement initiatives should also concentrate on (sub groups of) patients that could especially benefit from a personalized and patient-centred approach, as this might not be the same for every patient. We will continue on this statement more in depth. However, we should consider some interesting results for our entire patient group first, as we did find a significant improvement on the patient-centredness subscale 'Continuity of care'. This subscale received the lowest scores at baseline measurement and could therefore be considered as the subscale with the highest priority for improvement. Worse scores at baseline measurement might have motivated professionals just a bit more

to improve especially this patient-centredness domain. In addition, the continuity of care had the highest potential for improvement as well, which corresponds to the findings within other healthcare areas, showing that lower baseline scores are associated with the highest improvements.³² It should however be noted that the results on this subscale are on the margin of being statistically significant. Concerning the intervention costs, it is stimulating that the costs per patient per year were relatively low, especially for some of the clinics (median: €13, range €2 - €28). In general, costs per patient were lower for the larger clinics as the majority of their action points were executed by secretaries and nurses instead of gynaecologists, who are obviously much more expensive per hour. Clinics should therefore learn from each other to discover how similar improvement projects could be executed for relatively lower amounts of money. Also the most optimal balance between the effects and costs of a multifaceted improvement strategy for patient-centred care should be debated. In addition, the costs for additional healthcare consumption and productivity losses did not differ between the control and intervention groups, suggesting that the provision of patient-centred care is not associated with increased indirect medical and societal costs.

Figure 2
The case-mix adjusted effect of the intervention on the PCQ-Infertility total score for eight different patient profiles



Case-mix adjusted coefficients (B) with 95% confidence intervals and corresponding p-values are demonstrated here. In four out of eight possible scenarios (bold outlines), the intervention group had significantly higher scores on the PCQ-Infertility subscale total scale compared to the control group. For example, when patients had less than one year fertility care experience, were younger than 36 years and did not use CAM, the intervention group had a 0.14 points (95% CI=0.01-0.26) higher score on the PCQ-Infertility total scale than the control group.

Table 4**Overview of all costs from a societal perspective**

	Unit / Unit price (€)	Intervention	Control
Intervention costs			
<i>costs per year</i>		(€)	(€)
Audit and feedback			
Development of online questionnaire	Fixed / 845,00 ^a	845	-
Printing and shipping questionnaires	Questionnaire / 6,88 ^{a,b}	2408	-
Developing feedback reports	Hour / 32,58 ^a	489	-
Printing and shipping feedback reports	Report / 13,57 ^{a,b}	368	-
Total		4.110	-
Educational Outreach Visits			
Time expenses researcher	Hour / 32,58 ^{a,c}	671	-
Time expenses fertility team	Hour / 20,61 – 135,50 ^{a,c}	13.303	-
Treats EOVS	Treat / 2,35 ^d	353	-
Total		14.327	-
Patient-mediated interventions and action points			
Coordinating time researcher	Hour / 32,58 ^{a,c}	2.111	-
Developing newsletters	Hour / 32,58 ^a	201	-
Execution action points	Clinic / 0 – 9.294 ^a	43.879	-
Total		46.191	-
Total intervention costs		64.628	-
Median costs per clinic (range)		3.324 (959-11.550)	-
Median costs per patient per clinic (range)		13 (2-28)	-
Additional healthcare consumption^e			
<i>costs per patient per year, median (range)</i>		112 (0-8000)	112 (0-7056)
Productivity losses			
<i>costs per patient per year, median (range)</i>			
Fertility clinic visits			
Travel time		376 (0-6.467)	343 (0-4.720)
Waiting time		120 (0-2.451)	127 (0-1.470)
Appointment		148 (0-1.612)	159 (0-932)
Sickness absence		944 (0-31.468)	892 (0-47.203)

^a Clinical data refers to empirical data collected in this study.^b PostNL is the national mail delivery company taking care of the shipping of all questionnaires, feedback reports and newsletters: <http://www.postnl.nl/tarieven/partijenpost/binnenland>^c Recommended prices according to national guidelines for cost calculations in health care by Hakkaart-van Roijen *et al.*³⁹^d Bakery^e Additional healthcare consumption included the frequency of visiting six different healthcare providers per year (i.e. general practitioners, dieticians, physiotherapists, psychologists, alternative doctors and other medical specialists) multiplied by the Dutch medical costs per consultation, according to Hakkaart-van Roijen *et al.*³⁹

The most important strength of our study is the involvement of patients in the design, intervention and measurement of the study. We included more than 1500 infertile patients at both baseline and after measurement who received different treatments in all different phases ensuring representativeness of the Dutch infertile population. We measured the level of patient-centred care with a validated questionnaire asking for objective patients' experiences with care. Moreover, patients played an important role in the execution of the intervention, as former patients of the participating clinics took part in the EOVS. Finally, we corrected for clustering of patients within one clinic and adjusted for many background characteristics related to patient-centred care.

Some limitations of our study should also be taken into account. First, although our response rates seem sufficient (i.e. about 60%), the responses of many patients are still lacking which could have biased our results. For example, patients who were not satisfied with their care could not have completed the questionnaire. As we expect this to be true for patients in both the control and the intervention group, we consider the potential bias to be limited. Second, we performed our study within the area of Dutch fertility care. The results of our study might therefore be less representative for other healthcare areas or other countries. More research is needed to study the effect of such an intervention in a more broader and international setting. Within Europe however, comparable results could be expected as Dancet *et al.* showed that patients' preferences and needs in fertility care are similar throughout Europe.⁴⁰ Also the need for more patient-centred care has been describes in other healthcare areas.⁴¹⁻⁴³ Third, patient-centredness scores at baseline measurement were already reasonably high, which might have limited the effect of our intervention. This is supported by our results showing that only the 'continuity of care' subscale, receiving the lowest scores at baseline measurement, improved significantly. Possibly, the level of patient-centredness of Dutch fertility care was already rather good at the start of our study and a higher impact of the multifaceted approach could not have been expected.

The results of our study are of interest, as the evidence on how to improve patient-centredness in current healthcare is scarce. A review of Dwamena *et al.* showed that many interventions that promote patient-centred approaches were largely successful in teaching professionals new skills (e.g. clarifying patients' concerns and communicating about treatment options).⁴ However, when providers practiced these skills, it was not clear whether patients were more satisfied with their care.⁴ These conflicting results might be due to poor methodological quality or the use of less relevant strategies for care improvement.^{4,44} It might also be explained by the use of satisfaction surveys, which lack discriminative power as they often provide an overly optimistic picture of patients' perception of health

care.⁴⁵ We therefore asked for patients' more objective experiences with care instead of measuring patient satisfaction.

Despite this, our multifaceted approach did not reach a significant effect in our entire patient group. This could be due to an incomplete execution of the action points or to contamination because of major clinic changes that were executed by both the intervention and control clinics apart from the intervention (e.g. rebuilding of a clinic or change in the composition of the fertility team). An extensive and systematic process evaluation could be helpful to evaluate the actual exposure to the several elements of the multifaceted approach and to study whether a clinic's higher performance rate on the action plan relates to a higher increase in patient-centredness scores⁴⁶. Also reduced sensitivity of the PCQ-Infertility questionnaire could have contributed to a lack of effect. However, since the questionnaire had good psychometric properties and was able to discriminate between clinics in a previous study³⁰, other explanations may seem more obvious. We should therefore consider the significant interactions in our study in more detail, as they showed that we were able to increase patients' experiences with fertility care within specific patient groups.

First, patient-centredness of care significantly improved due to the multifaceted approach when patients started treatment during the intervention period (i.e. less than 12 months ago). In other words, our intervention seemed to be less effective for patients who were already under treatment before this study started. This suggests that patients are biased by their expectations and previous experiences with care, reducing the effect of the intervention, which is supported by the literature.^{47,48} Based on these results, we might state that improving patients' experiences should probably include the management of patients' expectations as a first step. The second characteristic influencing the effect of our intervention was women's age. Previous studies about the relation between patients' perspectives on fertility care and age did not always find significant associations.⁴⁹⁻⁵¹ An explanation for our study results might however be found in women's infertility problem itself. Because older women have decreasing per-cycle pregnancy rates, they might care less about their clinic's level of patient-centred care as getting pregnant is the only thing that is on their mind. This corresponds to the results of van Empel *et al.* showing that, compared to the level of patient-centred care, pregnancy rates were relatively more important to older patients than to younger patients.⁵² Third, the multifaceted approach appeared to be more effective when patients received some kind of CAM, such as hypnosis, homeopathy or acupuncture. About 20% of our patients used CAM, which is quite comparable with CAM use by infertile patients in other western countries.⁵³⁻⁵⁵ The relation between CAM and patient-centred care or its improvement has never been studied, but Nachtigall *et al.* suggest that cultural factors affect patients'

decision to choose for CAM.⁵⁶ Also in other healthcare areas, racial and ethnic differences in CAM use have been described.^{57,58} Presumably, CAM users are a unique patient group being more sensitive to the improvement of patient-centred care, as suggested by our study results. This is in concordance with the results of Vincent *et al.*, showing that CAM users belief in the value of treating the person as a whole and strive for more patient participation in one's care.⁵⁹

Due to the success of our intervention in specific patient groups, we might suggest focusing more on strategies and outcome measures at the sub group level or even at the individual level to improve the experiences of all our patients. In the last decades, physician-defined outcomes were mainly evaluated in research to determine the success of new therapies or medication.⁶⁰ Recently, important steps have been made towards the use of more patient-reported outcome measures as we also did in our study through the PCQ-Infertility questionnaire. The introduction of more individual reported outcome measures has now been suggested in the literature as a new and innovating step.⁶⁰⁻⁶² By putting the patient in the centre of outcome assessment, we could increase the interaction between patients and professionals and probably improve patients' experiences with care.⁶⁰ This is especially true in cases of a wide inter-individual variation in patients' needs and expectations, causing a limited responsiveness of a fixed-item instrument, such as the PCQ-Infertility.⁶¹ Future research should concentrate on the value of these individual outcome measures and its integration in usual care.

In conclusion, a multifaceted intervention including patient guided feedback and education does not improve care experiences of all patients in fertility care. An increase in the level of patient-centred care could however been achieved in patients who were under treatment after the intervention had started, were younger than 36 years and also used CAM. To increase the effect of our intervention in the future, we might have to focus on more individualized strategies and outcome measures by organizing our care around the patient.

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"WE WILL GET YOU PREGNANT, LADY!" THESE WERE LITERALLY THE WORDS OF THE DOCTOR WHO WOULD MAKE SURE THAT I GOT WHAT I WANTED: A BABY. OF COURSE, I KNEW THAT THE CHANCE TO ACHIEVE PREGNANCY WAS FAR FROM GUARANTEED, BUT IT USED TO SOUND LIKE: "PLEASE, DO NOT THINK TOO MUCH ABOUT IT. YOUR GYNÁECOLOGY WILL MAKE SURE THAT IT WILL ALL TURN OUT WELL." BUT NO, THIS WAS DEFINITELY NOT WHAT I EXPECTED FROM A PATIENT-CENTRED CARE? I CAN ANSWER THIS QUESTION WITH A CATEGORICAL NO. MY HUSBAND AND I EXPERIENCED DURING THE FIVE YEARS THAT WE WERE WAITING FOR A CHILD DURING THESE YEARS, WE WENT THROUGH DIFFERENT POSITIVE AND NEGATIVE EXPERIENCES. AFTER I HAD UNDERGONE A LAPAROSCOPY TO FIGURE OUT WHY I WASN'T GETTING PREGNANT, A NEW APPOINTMENT WITHIN TWO WEEKS TO START UP A NEW TREATMENT WAS SURPRISINGLY ANSWERED: 'THIS MUST BE A MISTAKE, BECAUSE IT'S TOO EARLY AFTER SURGERY. OBVIOUSLY, YOUR BODY NEEDS MORE TIME TO RECOVER.' THAT WAS REALLY WHAT THE DOCTOR HAD TOLD ME. BUT BEFORE I COULD GO HOME, MY COLLEAGUE, AGAIN, SHE ONLY CONFIRMED WHAT HER COLLEAGUE HAD SAID. I HAD TO RETURN WITHIN TWO WEEKS TO CONTINUE MY TREATMENT (AND I HAD TO TALK TO THE SECRETARIES, WHO WERE ALSO FIRM IN THEIR STATEMENTS. I COULD NOT GO HOME. THERE WAS NO PROBLEM TO SEE THE DOCTOR AND THERE WAS NOTHING TO BE DONE. I WAS VERY INSECURE AND HAD STRESSED ME OUT, WHICH OBVIOUSLY MADE IT EVEN MORE DIFFICULT TO SIT NEXT TO PATIENTS WHO WERE ALREADY PREGNANT AND TO FOLLOW THE PROGRESS OF THEIR PREGNANCIES TOGETHER. THAT'S GOOD FOR SOME, BUT NOT FOR INFERTILITY. IT WAS VERY HARD FOR ME TO SEE ALL THESE BIG BELLYS AND TO ASKED ME TO RETURN TO THE WAITING ROOM FOR A FEW MORE MONTHS. THERE I WAS, SITTING NEXT TO A MOTHER WITH A TWO-YEAR OLD CHILD. I WANTED TO PUT MYSELF IN HER SHOES AND FELT REALLY MISERABLE. BUT IT WAS NOT REALLY IMPRESSIVE. FOR EXAMPLE, IT HAPPENED SEVERAL TIMES THAT I HAD AN APPOINTMENT. OBVIOUSLY, THE DOCTOR WAS NOT AWARE OF THE FACT THAT HE HAD READ MY MEDICAL RECORD BEFORE I ENTERED THE ROOM. ALSO, THE INFORMATION WAS CONTRADICTORY. IT SEEMED LIKE ALL DOCTORS HANDLED OUR CASE DIFFERENTLY. IT SCARED ME A LITTLE BIT, AS I ALREADY FELT PSYCHOLOGICAL PRESSURE. THAT MY DOCTORS WERE ALL POINTING IN THE SAME DIRECTION. I FELT THAT OUR OWN DOCTOR SHOULD NEVER HAVE INTRODUCED THE IVF TREATMENT OPTIONS. VERY CONFUSING, AS WE DID NOT KNOW WHAT A NEW TREATMENT I READ ABOUT IN A MAGAZINE. OUR DOCTOR HAD SAID THAT OUR HOSPITAL, WHILE EXACTLY THE OPPOSITE WAS TRUE ACCORDING TO THE CRITERIA ELIGIBLE FOR THIS TREATMENT BEFORE. EVENTUALLY, I WAS TOLD THAT I WAS NOT BECAUSE OF THE WORSE COMMUNICATION, MY HUSBAND AND I HAD TO GO FOR AN ULTRASOUND CHECK-UP. A LOT OF SMALL FOLLICLES WERE VISIBLE. THAT WAS NOT WHAT I NEEDED TO ME, BUT MY DOCTOR JUST SAID: 'LOOKS FINE, BUT THIS IS NOT WHAT YOU NEED OF COURSE!' WELL, THAT WAS NOT WHAT I NEEDED TO SHARE, IS ABOUT MY ADMIS-
ALEIDA G. HUPPELSCHOTEN
ANNEMIEK W. NAP
DENISE A. PERQUIN
JAN A.M. KREMER
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CHAPTER 10

IMPROVING PATIENT-CENTREDNESS OF FERTILITY CARE: A PROCESS EVALUATION STUDY

SUBMITTED VIA

Abstract

Background

Process evaluations are of high importance when studying the effects of complex, multifaceted interventions. Results could namely be useful for adjusting improvement strategies to potentially more effective ones and for applying interventions to a larger scale. Therefore, we complement the findings of our randomized controlled trial (RCT) on the improvement of patient-centredness in Dutch fertility care by giving a detailed evaluation of our multifaceted intervention strategy.

Methods

We performed an observational study within 32 Dutch fertility clinics that were included in a RCT, studying the effects of a multifaceted strategy, including audit and feedback, educational outreach visits and patient-mediated interventions, on the level of patient-centred care. Questionnaires were used to study professionals' and patients' experiences with the intervention and clinics' exposure to the improvement strategy. We used multilevel linear regression analyses to study the relation between clinics' intensity rate on the intervention and the increase in patient-centredness and to identify determinants at the clinic level of an improvement in patient-centred care.

Results

In general, patients' and professionals' experiences with the intervention were mainly positive. Clinics came up with a median number of five action points (range: 3-7) for improving their patient-centredness levels and after one year, they finished 75% of their improvement plan (range: 20-100%). The numbers of clinics' executed improvement projects were not related to patient-centredness improvement. However, improvement in patient-centredness scores was significantly associated with higher levels of patient participation during the EOv, higher organizational group culture scores, and the absence of structured, weekly meetings to discuss all patients within the fertility team.

Conclusions

A multifaceted improvement strategy for patient-centred fertility care was positively evaluated. The resulting determinants of an improvement in patient-centredness showed that, in future projects, patients need to have a more important voice in the intervention and clinics should not only focus on their guidelines and protocols but listen to their individual patients' preferences

and needs as well. Finally, managers have to work on their teams to improve teamwork, especially to act as a group to reach their common goal of optimal patients' experiences with care.

Introduction

In previous decades, researchers mainly studied the effect of 'simple' interventions on predefined health outcomes, such as the effect of a new drug on survival or quality of life.^{1,2} However, due to the growing complexity of interventions and outcome measures over the last years, studies need to focus on more than their outcome alone.³ Studies investigating complex interventions, e.g. existing of different elements or executed at multiple levels, should at least be guided by an in-depth process evaluation^{2,3}, as the 'same' intervention could be implemented in different ways.^{3,4} Process evaluations are not interested in a study's success or lack of success, but take a look into the 'black box' of the intervention to see what actually happened.^{1,5} Therefore, they can be helpful in the interpretation of study results. For instance, by understanding the relationship between specific study elements and study outcomes.^{1,3} Moreover, having knowledge of the processes is important for the replication of interventions, for modifying an intervention to a potentially more effective one, and for applying interventions to a larger scale. Process evaluations might also aid the improvement of implementation science in general.² However, few complex interventions have included the evaluation of both the outcomes as well as the processes.²

We recently performed a randomized controlled trial in the area of fertility care that could benefit from a systematic process evaluation. In this study, we aimed for the improvement of patient-centred care, one of the six dimensions of quality of care, that takes into account individual patients' preferences and needs in healthcare.⁶ Because improvement potential for Dutch patient-centred fertility care had been shown in previous studies⁷⁻⁹, we designed a multifaceted strategy that existed of three elements (i.e. feedback reports, educational outreach visits and patient-mediated interventions) and was executed within 32 Dutch hospitals. Our results showed no significant improvement in the total level of patient-centred care one year after clinics were exposed to the multifaceted strategy. We did however show a significant improvement among specific domains of patient-centredness and in specific patient groups, indicating the need for a more in-depth understanding and evaluation of the multifaceted intervention.

Therefore, our main aim was to complement the findings of our RCT by giving a detailed account of the multifaceted intervention strategy for patient-centred fertility care. The process evaluation was based on three research questions:

- (i) How did both professionals and patients evaluate the importance, their expectations and experiences with the different components of the intervention?

- (ii) What was the relation between the improvement of patient-centred care and clinics' intensity on the multifaceted strategy?
- (iii) Which characteristics at the clinic level could be identified as determinants of an increase in the level of patient-centredness?

Methods

Design

We performed an extensive process evaluation study which belonged to a previously performed RCT about the improvement of patient-centred fertility care.¹⁰ Based on the framework of Hulscher *et al.*, we described the multifaceted intervention and we evaluated the intervention through the eyes of the study participants by asking them about the importance, expectations and experiences with the multifaceted strategy.⁵ Furthermore, we determined clinics' intensity on the intervention, as measured by the number of executed improvement projects on patient-centred care, in relation to clinic's levels of patient-centredness. Finally, we studied the relation between the improvement of patient-centred care in our intervention group and several characteristics at the clinic level, i.e. standard characteristics, clinics' culture types, and study related characteristics.

Setting

Clinical setting

Our study was performed in the area of fertility care. In the western world, one in six couples suffer from involuntary childlessness as they were not able to achieve pregnancy after twelve months of regular, unprotected sexual intercourse.¹¹⁻¹³ About 50% of these couples seek help for their fertility problem and start with an often lengthy period of fertility work up and treatment.^{14,15} In the Netherlands, fertility care is provided by three different types of clinics. Large IVF clinics perform all kinds of fertility treatments, while intermediate clinics refer their patients to an IVF clinic for the laboratory phase and embryo transfers of the *In Vitro* Fertilization (IVF) and Intra-cytoplasmic Sperm Injection (ICSI) treatments. The smaller Dutch clinics carry out only initial fertility assessment, ovulation induction (OI), and intra-uterine inseminations (IUI). Almost all Dutch fertility clinics are national health service funded and every Dutch citizen has a basic insurance coverage, covering treatment and medication costs for OI and IUI and three cycles of IVF / ICSI.

The randomized controlled trial

Our RCT was performed from June 2011 until April 2013 within 32 Dutch fertility clinics; eight IVF clinics, 16 intermediate clinics and eight smaller clinics. During baseline measurement, we measured clinics' levels of patient-centredness using the Patient-Centredness Questionnaire-Infertility (PCQ-Infertility) among 696 women who had undergone at least one cycle of fertility treatment in the previous three months. The validated questionnaire asked for objective patients' experiences with fertility care within 46 questions, divided into seven subscales; 'Accessibility', 'Information provision', 'Communication', 'Respect for patients' values', 'Continuity and transition', 'Patient involvement', and 'Staff's competence'.⁸ Subsequently, 16 clinics were randomized to the multifaceted improvement strategy and the remaining 16 clinics performed care as usual. After one year, we used the same PCQ-Infertility questionnaire to measure patient-centredness levels in a comparable group of 730 infertile women.

The intervention

In general, our intervention consisted of audit and feedback, educational outreach visits, and patient-mediated interventions. Furthermore, we used three tools (i.e. contacts by phone, newsletters, and an online study community) to monitor and stimulate the execution of the intervention during the entire study period. The first element of the multifaceted intervention, the feedback report, consisted of a personalized paper report with clinics' own results, benchmarked and presented in relation to all 32 participating clinics. The 16 intervention clinics were pointed at care aspects with priority for improvement by providing them with quality improvement scores (QI scores). These scores combined both patients' actual experiences with the different care aspects and their corresponding importance scores as collected in a previous study.⁸ One month after a clinic received the feedback report, its content was discussed with all members of the fertility team during an EOV. The EOVs were also attended by a quality officer of the hospital involved and a representative of the Dutch Patients' Association of Infertility 'Freya' who was a former patient of that clinic. Each EOV resulted in the definition of improvement goals and a clear action plan with allocation of tasks. Furthermore, clinics were offered several patient-mediated interventions. For example, they could decide to organize focus groups, or create online communities to gain more specific and detailed information from their patients' wishes and preferences with fertility care. These interventions were also taken up in the clinic's action plan. For monitoring and stimulating the execution of the action plan, the researchers contacted the team every two months and send them newsletters. Additionally, all professionals and former patients were invited to participate in an online study community to exchange their ideas and actions regarding the improvement of

patient-centred fertility care.

Process evaluation measures

Importance, expectations and experiences

We first evaluated the quality of the feedback reports and EOVs through a questionnaire for all EOv participants (i.e. professionals, quality officers and former patients) and gathered their experiences on a 5-points Likert scale (e.g. 1=the feedback report was not meaningful at all to 5=the feedback report was very meaningful). Furthermore, we asked the representatives of both the control and intervention clinics about the importance of the study, expectations regarding their clinic's results and their general experiences with the different study elements. To evaluate the study importance, gynaecologists had to distribute a hypothetical research subsidy of €1000 between three research subjects, i.e. effectiveness, safety and patient-centredness of fertility care. Subsequently, they provided their expected scores at after measurement (i.e. worse, comparable or better than baseline measurement) on the PCQ-Infertility total and subscale scores. Next, we evaluated professionals' general experiences with the study. For this part, the gynaecologists rated the quality of the research team and scored the meaningfulness of the different study elements on a scale from 0 to 10.

Clinics' intensity on the intervention

We evaluated clinics' intensity on the multifaceted intervention by collecting data regarding clinics' actual execution of the action plans at two moments; six months after the EOv and during after measurement. At six months, we contacted the representative gynaecologists by phone and asked for the number and kind of action points that were already executed. Then, during the after measurement, gynaecologists received a personalized questionnaire per mail in which they could indicate the number and kind of action points they had actually performed after one year. In addition, we were interested in clinic changes of both the intervention and control clinics that were executed apart from the RCT and that could have influenced the main outcome measure of our RCT, the level of patient-centredness. Therefore, we provided all gynaecologists with a list consisting of all action points of the 16 intervention clinics and asked them which of these care elements had been improved in the past year as well. We also left some room for other, spontaneous improvement projects that were not mentioned in the list, but could be considered as 'noise' in our study (e.g. a clinic's rebuilding or change in composition of the fertility team).

Determinants of improvement

We collected relevant potential determinants of an improvement of patient-centred care at the clinic level, based on the literature as possibly being related to patient-centredness or quality improvement in healthcare.¹⁶⁻²² The different clinic characteristics could be divided into three levels.

First, we gathered eight standard clinic characteristics, i.e. the clinic type, the number of gynaecologists, whether clinics had specialized fertility nurses and / or clinic psychologists, the presence of a separate waiting room and / or semen production room, and whether clinics had structured meetings to discuss all patients and / or regularly measured clinic's quality levels. Second, we identified the organizational culture of all clinics as a potential determinant of an improvement of patient-centred care using the Organizational Culture Assessment Instrument (OCAI). This validated questionnaire is based on the Competing Values Framework (CVF)²³⁻²⁵, which recognizes that a combination of four cultures coexist simultaneously within one hospital (i.e. group, rational, developmental, and hierarchical culture).²⁶ These four culture types relate to each other on a two-by-two matrix with two axis denoting both the flexibility (i.e. stabile vs. change) and orientation (i.e. internal vs. external) of the hospital to the outside world.^{23-25,27-29} To determine a clinic's organizational culture, we used the online version of the validated Dutch OCAI questionnaire at the start of the RCT.³⁰ For each of the six questions, members of the 32 fertility teams were asked to distribute 100 points across four statements representing the four culture types that best fitted their own clinic's organization. For each clinic, we determined the mean scores on the four culture types. In addition, we calculated the balance of the scores for the different culture types, using the Blau index as described in previous studies.^{26,27,31} A higher score on this index (scale 0-1) indicates a more even distribution of points among the four culture types.²⁶ The third group of potential determinants of patient-centredness improvement existed of eleven study related characteristics, e.g. a clinic's willingness to participate, the number of participants during the EOv, and consensus of the professional team regarding their action plan. Items reflecting an opinion on or attitude towards the fertility team (e.g. willingness to participate) were measured on a 5-points Likert scale by the main researcher who also led the EOvs (e.g. 1=no willingness to participate to 5= very high willingness to participate).

Data collection

We used four different questionnaires in this study to collect our data. First, at baseline measurement, we collected eight standard clinic characteristics as a potential determinant of patient-centredness improvement through an online questionnaire for the 32 representative gynaecologists. The non-responders were contacted by phone to guarantee a complete response. Meanwhile, the online OCAI questionnaire was sent to all 476 members of the 32 fertility teams to evaluate clinics' organizational culture types. We sent a reminder to the non-responders after two and after five weeks. A third questionnaire was used to evaluate the quality of the feedback reports and EOVS among all EOVS participants. The online questionnaire was sent shortly after the EOVS and non-responders received a reminder after two and after five weeks. The fourth and last questionnaire was used during after measurement. We composed a paper questionnaire for all 32 representative gynaecologists to evaluate the actual exposure to the study and their importance scores, expectations and experiences with the study. The questionnaires were personalized as every intervention clinic worked on their own, unique action plan and some of the questions were not applicable to the control clinics.

Statistical analysis

We first expressed all EOVS participants' evaluations of the feedback reports and EOVS and professionals' importance of the study, their expectations and experiences by their median values or numbers and corresponding percentages. When appropriate, differences between intervention and control clinics were calculated using chi-square tests or Mann-Whitney U tests.

For further analyses, we excluded the data of pregnant patients as it has been shown that the results of the PCQ-Infertility are confounded in this group.⁸ We described the number of action points that were defined by the intervention clinics during the EOVS and calculated the percentage of actual performed action points per patient-centredness dimension. Also the number of additional clinic improvements was described and compared to the number of spontaneous clinic improvements by the control clinics, using Mann-Whitney U tests. To analyse the relationship between patient-centredness improvement and the number of executed improvement projects (i.e. clinics' intensity on the intervention), we performed multilevel linear regression analyses to account for clustering of patients within clinics. The delta PCQ-Infertility total or subscales scores acted as the dependent variables. The number of improvement projects per patient-centredness dimension represented the independent variables. To come to these variables, we added the number of executed action points to the number of

additional clinic improvements for the intervention clinics. For the control clinics, we used the number of executed spontaneous clinic improvements.

To analyse determinants at the clinic level of the effect of the multifaceted intervention, we first performed a series of univariate linear regression analyses with the delta PCQ-Infertility total score as the dependent variable. Data of the control group were excluded as the multifaceted improvement strategy did not aim at these clinics and especially the study related clinic characteristics could not be gathered in this group. In the univariate analyses, all clinic characteristics (i.e. standard, culture and study related characteristics) acted as the independent variables and only characteristics with $p < 0.15$ were selected for multivariate analysis. Next, we tested for significant correlations between the selected variables using correlation analyses with Spearman's ρ . In case of two strongly correlated variables ($\rho > 0.60$), we gave preference to the characteristic that was clinically and theoretically most relevant. Then we included these characteristics in a multilevel multivariate linear regression model and excluded the statistically insignificant variables to come to our final model. Finally, we calculated the explained variance (R^2), indicating what percentage of variance in patient-centredness improvement is attributable to the characteristics that were part of our final model.

Statistical significance was set at $P < 0.05$ and our analyses were performed using SPSS (version 20.0 for Windows®, SPSS Inc., Chicago, IL, USA).

Results

At baseline measurement, 1620 patients were invited to participate and 946 patients (response 58.4%) completed the PCQ-Infertility questionnaire. A total of 250 pregnant patients were excluded and data of 696 patients were consequently left for analysis. Shortly after baseline measurement, two intermediate fertility clinics merged to one new clinic. As it concerned one control clinic and one intervention clinic, we decided to exclude these clinics from our study to avoid extensive contamination of our intervention. After measurement was thus performed among 30 clinics, 15 intervention and 15 control clinics, and we invited a total of 1565 patients. The PCQ-Infertility was completed by 946 patients (response rate 60.4%). After excluding 216 pregnant patients, 730 patients were eligible for analysis.

Importance, expectations and experiences

The EOVs were attended by 133 members of the fertility teams, 10 quality officers and 12 former patients. A total of 58 fertility team members (43.6%), five quality officers (50%), and ten former patients (83.3%) completed the online questionnaire about the quality of the feedback reports and EOVs. These results are presented in table 1, showing that only 50% of the fertility team members had read the feedback report on forehand. However, the majority of respondents (80-100%) rated the general quality and meaningfulness of the reports as good to very good. Participants' personal input during the EOVs was considered low with the lowest input for quality officers (none of the quality officers rated their input as high or very high). Almost all fertility team members and quality officers believed that the action plan would be executed and that their clinics' level of patient-centredness would improve. However, only 50% and 70% of the former patients believed in the execution of the action points and improvement in patient-centredness, respectively.

Table 1

Baseline characteristics of EOv participants and their evaluation of the feedback reports and EOvs

	Members of fertility team	Quality officers	Former patients
Baseline characteristics			
Present on EOv, <i>number</i>	133	10	12
Completed questionnaire, <i>number (%)</i>	58 (43.6)	5 (50.0)	10 (83.3)
Feedback report (%)^a			
Read the report on forehand	50	60	100
General quality	100	80	90
Meaningfulness	92	100	100
EOv (%)^a			
Personal input in EOv	21	0	10
The atmosphere	98	100	90
Listening to each other	95	100	100
Willingness to change	96	100	90
Supporting the action points	98	100	80
Believing in execution of action points	89	100	50
Improving level of patient-centredness	93	100	70

^a Percentage of people who rated the statements on the feedback report and the EOv with no. 4 (e.g. 'good' or 'high') or no. 5 (e.g. 'very good' or 'very high') on a five-points Likert scale.

The evaluations provided by the representative gynaecologists are presented in table 2. Considering the study's importance, gynaecologists seemed to spend the highest amount of research money on patient-centred fertility care and the lowest amount on safety. No significant differences could be detected between the intervention and control group, although the intervention group tended to place more money on effective fertility care than the control group ($p=0.06$). Next, 71.4% of the gynaecologists from the intervention group expected to have better results at the after measurement compared to baseline measurement. The highest improvement was expected on the patient-centredness domains 'Information provision' and 'Continuity of care' and no one expected lower scores compared to baseline. The gynaecologists from the control group had significantly different expectations as only 33.3% expected higher scores compared to baseline measurement and 66.7% was expecting comparable scores ($p=0.04$). Also in this group, no lower scores were presumed at the after measurement compared to baseline. Further, gynaecologists were rather positive about their experiences with the study. High ratings were provided on the majority of study elements, with the highest scores on the feedback reports, educational outreach visits, participation of former patients and contacts with the researcher. The online community, which was only seldom used by the study participants, received the lowest median rating of 5 (range 1-9).

Clinics' intensity on the intervention

During the EOVS, the fertility teams, quality officers and former patients came up with a total of 76 action points, which was a median number of five action points per clinic (range: 3-7). The majority of action points considered the improvement of information provision ($n=29$), respect for patients' values ($n=15$) and continuity of care ($n=11$). No clinics focused on the improvement of staff's competence. Ten action points could not be divided into one of the seven patient-centredness dimensions (e.g. 'improving waiting times for a new appointment' and 'improving the delivery procedure of semen in the laboratory for men'). These action points were therefore summarized within an additional dimension, i.e. 'Organisation of care'. Table 3 shows both the total and median number of action points per clinic, the percentages of action points that were actually performed and the executed additional and spontaneous clinic improvements. At six months, clinics had finished 29 action points (i.e. 33%); one clinic already performed the entire action plan while four clinics did not start working on their action plan yet. After one year, the median percentage of executed action points was 75%, ranging from 20 to 100%. Four of the fifteen intervention clinics were able to perform their entire action plan within the study period. Furthermore, the intervention clinics focused on the improvement of 88 additional care aspects apart from the

action plan, which was a median number of six additional improvement per clinic. The control clinics performed 75 spontaneous self-reported care improvements (median = 3, range 0-14). No significant differences in the executed additional and spontaneous clinic improvements existed between the intervention and control group ($p=0.217$). Furthermore, results from the regression analyses showed no significant association between the number of improvement projects and the improvement in patient-centred care.

Table 2

Study evaluation on three levels: the importance, professionals' expectations and experiences with the study

	Intervention clinics	Control clinics	p-value
IMPORTANCE			
Division of a research subsidy of €1000			
<i>(median, range)</i>			
Effectiveness	400 (0-800)	300 (0-1000)	0.06
Safety	200 (0-300)	250 (0-300)	0.35
Patient-centredness	400 (100-900)	500 (0-1000)	0.22
EXPECTATIONS			
Changes in patient-centredness scores			
<i>(better / same / worse, %)</i>			
Total score	71.4 / 28.6 / 0.0	33.3 / 66.7 / 0.0	0.04*
% improvement (median, range)	25 (10-40)	10 (10-40)	0.37
Accessibility	50.0 / 50.0 / 0.0	33.3 / 66.7 / 0.0	0.36
Information provision	57.1 / 42.9 / 0.0	60.0 / 33.3 / 6.7	0.57
Communication	42.9 / 50.0 / 7.1	33.3 / 66.7 / 0.0	0.45
Respect of patients' values	21.4 / 78.6 / 0.0	6.7 / 93.3 / 0.0	0.25
Continuity of care	57.1 / 28.6 / 14.3	13.3 / 73.3 / 13.3	0.03*
Patient involvement	14.3 / 71.4 / 14.3	20.0 / 73.3 / 6.7	0.76
Staff's competence	21.4 / 78.6 / 0.0	13.3 / 86.7 / 0.0	0.56
EXPERIENCES			
Quality of research team			
<i>(too little / good / overload, %)</i>			
Accessibility by phone or e-mail	0.0 / 100.0 / 0.0	-	
Knowledge	0.0 / 100.0 / 0.0	-	
Willingness to help	0.0 / 100.0 / 0.0	-	
Meaningfulness of study elements			
<i>(0-10, median (range))</i>			
Feedback report	9 (7-10)	-	
Educational Outreach Visit	8 (6-10)	-	
Participation of former patients during EOv	8 (2-8)	-	
Participation of quality officer during EOv	7 (1-9)	-	
Online community	5 (1-9)	-	
News letters	7 (3-9)	-	
Contacts with researcher every two months	8 (7-9)	-	

* Significant difference ($p<0.05$) between the intervention and the control group after using Chi-quadrade tests.

Determinants of improvement

All clinic characteristics are presented in table 4 together with the results of the univariate regression analyses. A total of six clinic characteristics were associated with the delta PCQ-Infertility total scores ($p < 0.15$) and therefore selected as potential determinants of an improvement of patient-centred care. Subsequently, two characteristics were excluded due to collinearity; 'Structured meetings to discuss all patients' was chosen in favour of 'Number of gynaecologists' (Spearman's $\rho = 0.625$) and 'Clinic type' was chosen in favour of 'Number of functions present at EOVS' (Spearman's $\rho = 0.807$). After manual backward elimination, three characteristics were significantly related to an improvement in patient-centred care. First, when adjusted for the other clinic characteristics, a higher score on the organizational group culture was significantly related to a higher improvement score ($B = 0.014$; 95% CI = 0.006-0.021; p -value = < 0.01). Second, a higher input of former patients during the EOVS was significantly associated with higher adjusted patient-centredness improvement scores ($B = 0.051$; 95% CI = 0.015-0.088; p -value = < 0.01). Third, clinics having a structured meeting to discuss all patients had significantly lower delta PCQ-Infertility total scores ($B = -0.138$; 95% CI = -0.256 - -0.020; p -value = 0.02). It turned out that 8.9% of the variance in delta PCQ-Infertility total scores (i.e. R^2) was attributable to these three clinic characteristics.

Table 3

Execution of action points and additional clinic improvements

	Intervention clinics				Control clinics
	Defined action points EOVS	Executed action points: 6 months	Executed action points: one year	Executed additional improvements	Executed spontaneous improvements
	<i>n (%)</i>	<i>n (%)</i>	<i>n (%)</i>	<i>n (%)</i>	<i>n (%)</i>
Total	76 (100)	29 (38.2)	55 (72.4)	88 (100)	75 (100)
Accessibility	7 (9.2)	6 (85.7)	7 (100.0)	6 (6.8)	4 (5.3)
Information provision	29 (38.2)	12 (41.4)	22 (75.9)	23 (26.1)	23 (30.7)
Communication	2 (2.6)	0 (0.0)	1 (50.0)	0 (0.0)	0 (0.0)
Respect of patients' values	15 (19.7)	2 (13.3)	11 (73.3)	19 (21.6)	18 (24.0)
Patient involvement	2 (2.6)	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)
Continuity of care	11 (14.5)	6 (54.5)	8 (72.7)	16 (18.2)	4 (5.3)
Staff's competence	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Organisation of care	10 (13.2)	3 (30.0)	4 (40.0)	24 (27.3)	15 (20.0)
	<i>n (range)</i>	<i>% (range)</i>	<i>% (range)</i>	<i>n (range)</i>	<i>n (range)</i>
Clinic level^a	5 (3-7)	33 (0-100)	75 (20-100)	6 (2-11)	3 (0-14)

^a Clinics' median numbers (*n*) or median percentages (%) with corresponding ranges are presented here.

A Mann-Whitney *U* test showed no significant difference in the median number of additional clinic improvements (intervention clinics) and the median number of spontaneous clinic improvements (control clinics).

Multilevel linear regression analyses showed no significant association between the improvement of patient-centred care (delta PCQ-Infertility total and subscale scores) and the number of improvement projects per clinic (i.e. clinics' intensity on the intervention).

Table 4**Clinic characteristics and results of univariate regression analyses with delta PCQ-Infertility total scores of 377 non-pregnant patients from 15 intervention clinics**

Standard clinic characteristics		Univariate analyses	
		<i>B</i>	<i>p-value</i>
Clinic type			
Large IVF clinic, <i>n</i> (%)	5 (33)	<i>Ref</i>	-
Intermediate clinics, <i>n</i> (%)	5 (33)	0.08	0.13*
Small clinics, <i>n</i> (%)	5 (33)	0.10	0.06*
Number of gynaecologists, <i>median (range)</i>	3 (1-7)	0.03	0.15**
Specialized fertility nurses, <i>n</i> (%)	10 (67)	-0.05	0.46
Presence of clinic psychologist(s), <i>n</i> (%)	10 (67)	0.06	0.43
Separate waiting room, <i>n</i> (%)	4 (27)	0.05	0.58
Structured meetings to discuss all patients, <i>n</i> (%)	11 (73)	-0.13	0.09*
Separate semen production room, <i>n</i> (%)	10 (67)	-0.09	0.17
Regularly measuring clinic's quality levels, <i>n</i> (%)	11 (73)	-0.03	0.67
Organizational culture (0-100), <i>median (range)</i>			
Group	39.4 (27.5-47.4)	0.01	0.13*
Rational	20.5 (16.1-24.5)	-0.05	0.22
Developmental	13.6 (8.7-18.5)	-0.01	0.29
Hierarchical	26.4 (18.5-34.6)	<-0.01	0.70
Culture balance (0-1), <i>median (range)</i>	0.71 (0.68-0.74)	-0.02	0.21
Study characteristics			
Willingness to participate, <i>n</i> (%) ^a	9 (60)	-0.03	0.46
Duration of EOVS, <i>min (range)</i>	75 (50-120)	<0.01	0.96
No. of EOVS participants, <i>median (range)</i>	13 (4-16)	<-0.01	0.42
No. of functions present at EOVS, <i>median (range)</i>	5 (1-9)	-0.03	0.06**
Input quality officer during EOVS, <i>n</i> (%) ^a	5 (33)	0.03	0.17
Input former patients during EOVS, <i>n</i> (%) ^a	4 (27)	0.05	0.07*
Preparation team, <i>n</i> (%) ^a	4 (27)	<0.01	0.94
Consensus action plan, <i>n</i> (%) ^a	9 (60)	-0.04	0.24
Enthusiasm regarding action plan, <i>n</i> (%) ^a	8 (53)	-0.02	0.55
No. of action points, <i>median (range)</i>	5 (3-7)	0.02	0.40
% of executed action points, <i>median (range)</i>	75 (20-100)	<0.01	0.32

^a Numbers and percentages of clinics scoring 4 (e.g. 'good') or 5 (e.g. 'very good') on a five-points Likert scale. Results based on the data collected by the main researcher.

* Characteristics associated with the delta PCQ-Infertility total score (p -value<0.15) and therefore allowed in multivariate analysis.

** The characteristics 'Number of gynaecologists' and 'Functions during EOVS' were also associated with the delta PCQ-Infertility scores, but due to collinearity with respectively the items 'Structured meetings to discuss all patients' (Spearman's ρ =0.625) and 'Clinic type' (Spearman's ρ =0.807) we excluded these variables from further analysis.

Discussion

This study gave us the possibility to take a look into the 'black box' of our RCT and enhance our understanding of professionals' and patients' experiences with the multifaceted improvement strategy, clinics' intensity on the intervention and clinic characteristics being related to patient-centredness improvement. The study received high satisfaction ratings by both the patients and professionals and, in general, the intervention was carried out as planned. Unfortunately, the number of executed improvement projects by both the intervention and control clinics could not be related to the improvement of patient-centred care. We did however find some important clues on how to increase the effect of the multifaceted intervention in the future, as an increase in patient-centredness scores was related to higher levels of patient participation, higher organizational group culture scores, and the absence of structured, weekly meetings to discuss all patients within a fertility team. Our results are therefore highly relevant, as studies regarding the improvement of patient-centred care were already scarce, but no literature was available on the in-depth process evaluation of such a study. Our results could therefore be useful for adjusting the improvement strategy to a potentially more effective one, and for increasing our knowledge about more optimal implementation of complex interventions in general.

Because this study was performed within more than one third of all Dutch hospitals and among more than 3000 infertile patients, we can ensure representativeness of the Dutch infertile population. Another important strength of this study is the collection of many clinic characteristics that could have influenced the improvement of patient-centred care. We did not only consider standard clinic characteristics, such as the number of gynaecologists, but also included study related characteristics and clinics' organizational culture types. So far, the organizational culture of a clinic has never been related to objective patients' experiences with patient-centred care before.

When interpreting the results of our study, some limitations should be taken into account as well. First, we measured the actual exposure to the multifaceted intervention through a questionnaire for the representative gynaecologists. Therefore, the percentage of executed action points depended on the opinion of the gynaecologist, instead of on objective facts or measures. From the literature, it is known that professionals often overestimate their performance on patient-centred aspects of their care.³²⁻³⁴ This corresponds to our own findings as many gynaecologists in the intervention group (i.e. 71.4%) expected an improvement in their clinics' level of patient-centredness. We tried to prevent this potential bias by asking for more details regarding clinics' performance on the action plan (e.g. who executed the action points, how many hours did this person spend on it, etc).

In case of ambiguity, we contacted the gynaecologists by phone to make clear whether an action point was really executed or not. Second, only a relative small proportion of fertility care members completed the questionnaire about the quality of the feedback reports and EOVs (i.e. response rate was 43.6%). It is possible that only professionals who were positive about the study responded, which might have biased our results. In addition, this response rate could tell us something about professionals' motivation to participate in this patient-centredness study, especially when comparing it to the response rate of the former patients, which was almost twice as high (i.e. 83.3%). A comparable conclusion could be drawn from another part of the questionnaire, as only half of the fertility team members had read the feedback report on forehand compared to 100% of the former patients. Possibly, an improvement program for patient-centred care should focus more on professionals' behaviour and motivation. This is also suggested by O'Donnell, who developed a framework for behaviour change among healthcare professionals in which the enhancement of professionals' motivation has a prominent place.³⁵ Also Rogers *et al.* showed that a high degree of professionals' motivation is needed in interventions that ask for active participation of health professionals.³⁶ Obviously, future studies should take this into account.

This study is an example of an in-depth evaluation of a multifaceted improvement strategy for patient-centred care. Also previous research has already focused on the evaluation of multifaceted interventions. However, both in the area of fertility care as well as in other healthcare areas, the majority of studies concentrate on the implementation of guidelines instead of on patients' care experiences in order to improve quality of care.^{2,4,37-39} These studies have mixed findings, as for example, Mourad *et al.* found no improvement in fertility guideline implementation after performing a multifaceted strategy that was both professional and patient orientated.³⁸ Ouwens *et al.* however showed an improvement in several management aspects (e.g. support for stopping smoking and nutrition support) after implementing an integrated care program for patients with head and neck cancer.³⁷ Because our research could hardly be compared to these studies, we should consider our study as an interesting addition to the existing process evaluation literature, by stressing out the importance of evaluating interventions that aim at patient-centredness of care as well.

Some recommendations and lessons can obviously be learnt from this process evaluation, for example about the length of the improvement strategy. In the literature, it is recommended to repeat a cycle of audit and feedback with regular intervals, but the length of these intervals is not clear yet.⁴⁰ In our study, only one-third of the action plans were performed after six months. After one year, already 75% of the action plans were executed, which might indicate that we did not reach the maximum improvement potential yet and higher percentages

could be reached after for example two years. This should be an interesting topic for future research. When focusing on the results we obtained after one year of intervention, we can state that still a high percentage of action points were executed by the clinics. However, clinics' individual scores ranged from 20 to 100%, indicating that some clinics only performed a very small part of their improvement plan. Some gynaecologists mentioned a lack of time or having different priorities as reasons for not performing one or more action points. Because we did not explicitly ask for these reasons in our questionnaire, we cannot draw conclusions on these statements. However, they seemed to be in line with the available literature⁴¹⁻⁴³ and more attention should consequently be paid to these barriers when aiming at the improvement of patient-centred care in the future.

In this process evaluation study, we did not find a relation between the number of clinics' improvement projects and the improvement in patient-centredness scores. This could mean that the content of the action plans was not optimal yet, or that the execution of the action plans could still be improved. A lack of association might also be due to the 'noise' of additional and spontaneous improvement projects by both the intervention and control clinics. The total number of executed additional improvement projects by the intervention clinics was even higher than their number of executed action points. Although we did take these additional action points into account in our analyses, it seems natural that the additional improvements were less focused on what clinics actually needed regarding their level of patient-centredness. This could have biased our study results. For future studies, it would be very difficult to prevent this potential bias, but being more aware of this 'normal improvement behaviour' would already be an important step forwards.

Recommendations for daily clinical care and future research should also be based on the three clinic characteristics that were related to an increase in clinics' patient-centredness levels. It should however be mentioned that only a small proportion of variance in patient-centredness scores (i.e. 8.9%) could be attributed to these characteristics and many other, still unknown factors will be of importance as well. Nevertheless, a significant association was found between patient-centredness improvement and the absence of structured, weekly meetings to discuss all patients within the fertility team. This is an interesting finding as it suggests that clinics with structured meetings have a more standardized and protocol-guided way of treating patients instead of aiming at patient-centred care by listening to their patients' individual expectations, preferences and needs. This is in line with the debate of Jozien Bensing, who discussed already in 2000 that both paradigms of evidence-based and patient-centred medicine belong to different worlds and are not integrated.⁴⁴ Our results now suggest that if we really

want to improve patients' experiences with healthcare, we have to focus more on patient-centred aspects of care by for example discussing patients' individual expectations and preferences during treatment. Also a strong focus on patient participation in healthcare has been associated with patient-centred medicine⁴⁴, which corresponds to our second determinant for improving patient-centredness, i.e. more intense patient participation during the EOV. Apparently, action plans of clinics with an intense patient participation during EOV were more optimally adjusted to patients' wishes and needs than the action plans of clinics with less or even no patient participation. Patients should therefore not only be involved in the development of guidelines⁴⁵⁻⁴⁷ and in decision-making regarding their own treatment⁴⁸⁻⁵⁰, but in improvement projects about patient-centred care as well. The final determinant of an increase in patient-centred care was a higher group culture score, which seems to be in line with the literature showing that more teamwork relates to patients' satisfaction with care.^{17,51-53} Meanwhile, Marshall *et al.* debated that, in case of group cultures, quality improvement is difficult due to clinics' tendency to be 'inward looking' and inflexible.⁵⁴ Our results indicate that 'inward looking' can also be considered as a positive outcome, as these teams were able to work together and improve important patient-centred elements of their care. Therefore, striving for a more group-based organizational culture is an ambitious but important goal for the future. Especially managers and other professionals on executive positions should have a leading role in this process, for example by implementing existing frameworks or strategies for improving teamwork in healthcare.⁵⁵⁻⁵⁷ Because studies regarding organizational culture types are still limited in medical care, our results should be motivating for others to perform more research regarding this interesting subject.

In conclusion, evaluation of a multifaceted improvement strategy for patient-centred fertility care revealed that both patients and professionals had both positive experiences with the intervention, although professionals' motivation for participation could still be increased. Clinics performed their action plans for patient-centredness improvement largely as planned, but our study results were likely to be influenced by the noise of additional improvement projects of all participating clinics. A lesson learnt for future improvement studies on patient-centredness is that patients should have an important voice in this research. Moreover, clinics should strive for a more optimal balance between evidence-based and patient-centred medicine by not only focusing on their guidelines and protocols but by listening to their individual patients' preferences and needs. Finally, managers should work on their teams to improve teamwork and work together as a group towards their common goal of optimal patients' experiences with care.

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CHAPTER 11

GENERAL DISCUSSION

General Discussion

This thesis is about improving patient-centredness of Dutch fertility care. In the first part of this thesis, we explored the concept of patient-centred fertility care extensively, as relevant information regarding this subject was lacking. In the second part, we tried to come to an optimal improvement design for patient-centred care and studied the effect in a large randomized trial.

In this final chapter, we present answers to the eight research questions we stated in the general introduction. Subsequently, we will discuss our main findings in light of the available literature and point out some methodological considerations. This chapter concludes with our recommendations for patients, healthcare providers, policy makers and future research.

Answers to the research questions

Question 1 - How do patient-centred care, quality of life (QoL) and distress relate to each other in fertility care?

The results of chapter 2 show us that patient-centred fertility care and infertile patients' QoL and levels of distress (i.e. anxiety and depression) are related in women. High psychosocial well-being could therefore lead to positive care experiences and improved patient-centredness of care. However, because of the cross-sectional design of our study, associations could also be presented the other way around, i.e. more patient-centred care leads to better QoL and lower levels of anxiety and depression. If this is true, our results should motivate professionals even more to provide patient-centred care as it would improve their patients' psychosocial well-being. To find out the actual direction of the relationship between patient-centredness and psychosocial well-being, future research should focus on identifying causal relationships among these variables. For now, we can state that patient-centred fertility care, QoL and distress are related in a group of infertile women, stressing out the importance of a comprehensive approach when providing care to these women suffering from infertility.

Question 2 - Do infertile women and their partners differ regarding their fertility care experiences, quality of life and risk factors for emotional problems?

We explored the possible differences between infertile women and their partners in two chapters. First, in chapter 3, we found that both members of the infertile couple evaluate their overall experiences with patient-centred fertility care comparable. Only small differences were detected on two of the seven domains of patient-centred care (i.e. 'Respect for patients' values' and 'Patient involvement'), but these results were considered as not being clinically relevant. When aiming

at the improvement of patient-centred care, it is important to be aware of the similar care experiences within the infertile couple.

However, on patients' level of QoL and risk factors for emotional problems, clear differences were found between infertile women and their partners, as described in chapter 4. Infertile women appeared to have lower levels of fertility-related QoL than their partners. Moreover, infertile women had more risk factors for emotional problems than their partners, and differed in the kind of risk factors. Therefore, both members of the infertile couple might be vulnerable to different sources of psychological stress. This stresses out the importance of identifying risk factors for emotional problems for both members of the infertile couple separately. Only then, infertile women and partners can receive the tailored psychosocial support they need.

Question 3 - Can we use the level of patient-centredness as a predictor for dropout in fertility care?

We performed a prospective, longitudinal study on the association between clinic factors, including the level of patient-centred care, and premature dropout in fertility care. The results of this study, as described in chapter 5, showed no significant relation between patient-centred fertility care and dropout. This suggests that patient-centredness is no optimal predictor for dropout in fertility care. In our additional analysis however, we found significant associations between patient-centredness and dropout in specific patient groups. First, patients undergoing non-ART treatments (e.g. intra-uterine inseminations) had significantly lower scores on the PCQ-Infertility subscale 'Respect for patients' values' when they dropped out. Moreover, patients who received ART treatments (e.g. in *vitro* fertilization) and, subsequently, dropped out had significantly higher scores on the PCQ-Infertility subscale 'Patient involvement' than those who continued treatment. Further research should indicate if and to what extent patient-centredness of care could be used as a predictor for other patient groups.

Question 4 - What is the monetary value of patient-centred fertility care?

Based on the results of a discrete choice experiment, we can state that infertile patients take the level of patient-centredness into account when choosing a fertility clinic. They even wanted to pay a considerable amount of money for more patient-centred fertility care. In chapter 6, we showed that patients were willing to pay a median amount of €463 for a relevant one-step increase in patient-centred care. We also putted this in perspective to the willingness-to-pay (WTP) for more effective fertility care: for a clinic offering one percent higher pregnancy rates, patients were willing to pay €107. Also health insurers, which can be considered as

the patients' representatives in the Dutch healthcare setting, pay attention to the patient-centredness of care when purchasing care for their insurance company. Healthcare purchasers' median WTP for more patient-centred care was €191. For one percent higher pregnancy rates, they were willing to pay €60. These results reflect the importance of patient-centredness in healthcare, as clinics' levels of patient-centred care significantly influenced both patients' and health insurers' choices for a clinic. This should motivate both professionals and policy makers to aim at the improvement of patient-centredness in current healthcare. Our results might even suggest that the improvement of patient-centred care could be stimulated by introducing optional copayments for clinics offering more patient-centred care. Future research should focus on the feasibility of patients' optional copayments for patient-centred care by studying for example practical, social and ethical issues.

Question 5 - What is the effect of audit and feedback on the improvement of patient-centred fertility care?

In chapter 7, we described the effect of audit and feedback on the level of patient-centred fertility care. A total of 15 clinics received a feedback report, showing their performance on patient-centred fertility care in relation to all participating clinics. Two years after the feedback was provided, we found no significant improvement on the level of patient-centred care, indicating that solely audit and feedback is not enough for improving patients' experiences with patient-centred fertility care. Our results also showed that only five of the fifteen clinics had undertaken some kind of action towards improvement after they had received the feedback report. Possibly, providing professionals with feedback regarding their clinic's level of patient-centred care does not result in sufficient motivation to actually come to improvement. Alternative strategies are therefore needed to further optimize the level of patient-centredness in fertility care.

Question 6 - Which aspects should be included into an optimal improvement design for patient-centred fertility care according to professionals?

In a qualitative research, which was also described in chapter 7, we interviewed different fertility care professionals about their views on providing and improving patient-centred care. First, professionals appeared to be aware what patient-centred care is and they provided many suggestions on how to improve it. However, professionals' motivation to change and their ability to translate feedback about their own performance into an effective quality improvement strategy were suboptimal. We considered this as the key issues to come to improvement. Publically publishing clinics' results on their level of patient-centred care might be a tool to actually increase professionals' motivation for change. For increasing

professionals' knowledge about the way they provide patient-centred care and translating this into an actual improvement plan, the use of detailed, concrete and individualized feedback to professionals was recommended. Subsequently, according to the professionals, the feedback must be discussed within the professional team to define improvement goals and develop a clear action plan. To achieve sustainability with improvement goals, the execution of the action plan should receive follow up, and the possible effects must be re-measured.

Based on the input of this qualitative study and additional literature concerning the improvement of patient-centred care, we designed a multifaceted improvement strategy for Dutch fertility care. The multifaceted approach consisted of audit and feedback, educational outreach visits and patient-mediated interventions.

Question 7 - What is the (cost-)effectiveness of a multifaceted approach on the improvement of patient-centred fertility care?

We performed a large cluster-randomized trial on the improvement of patient-centred fertility care by means of a multifaceted approach. In chapter 9, both the effects and the costs from a societal perspective of this multifaceted improvement strategy are described, showing no significant improvement on the total level of patient-centred fertility care. Also when taking into account clinics' intensity on the intervention (i.e. the number of executed improvement projects per clinic) no significant improvement in patient-centred scores could be found, as presented in chapter 10. Therefore, we can state that a multifaceted intervention, including patient-guided feedback and education, does not have the capacity to improve patients' care experiences for all patients in fertility care. However, scores on the patient-centredness domain 'Continuity of care' were significantly higher (i.e. better) in the intervention group compared to the control group. Because this domain received the lowest scores during baseline measurement, our intervention seemed to be successful in improving care elements with the highest priority for improvement. The median total costs of the execution of the multifaceted approach per clinic were €3.324 per year (range €959-€11.550). The median costs per patient per clinic were €13 (range €2-€28). The additional health care consumption and productivity losses did not significantly differ between the intervention and the control group, which suggests that the provision of patient-centred care is not associated with increased indirect medical and societal costs.

Question 8 - Which determinants at the patient and clinic level are associated with an increase in the level of patient-centredness?

Next to the effect and costs of the multifaceted approach, we also explored the influence of different determinants at the patient and clinic level on the effect of

the multifaceted intervention. In chapter 9, we found three patient characteristics being significantly associated with an increase in patient-centred fertility care. First, our multifaceted improvement strategy was successful when patients recently started treatment (i.e. less than 12 months ago). Second, patients who were younger than 36 years were more sensitive to the effect of the multifaceted approach, and third, patient-centredness levels significantly improved in the intervention group compared to the control group when patients received complementary and alternative medicine (CAM). This suggests that specific patient groups could benefit from a patient mediated improvement strategy for patient-centred care. Furthermore, chapter 10 provided us with three clinic characteristics that were significantly associated with a higher increase in patient-centredness levels in the intervention group. This was true for clinics with a more intense patient participation during the study, clinics having higher group culture scores, and clinics that did not have structured, weekly meetings to discuss all patients, reflecting the level of 'protocolized thinking' within a clinic. These results are of high importance for professionals, managers, and researchers when taking a next step towards better patients' experiences with patient-centred care.

Interpretation and discussion of the main findings

"Improving patient-centredness of care!" In this thesis, we strived for this ambitious but important goal in current healthcare, reflecting the numerous studies that have explored the concept of 'patient-centredness' in recent years. In these studies, patient-centredness is recognized as a multidimensional concept¹⁻³, including domains on the organizational level, such as information provision and continuity of care, but also domains on the human level, e.g. communication and respect for patients' values.⁴ A complex concept thus, which might be difficult to measure, but maybe even more difficult to improve. We used a validated questionnaire, asking for objective patients' experiences with care to measure clinics' levels of patient-centred fertility care⁵ and used these results to offer feedback to the clinics. However, the use of solely audit and feedback turned out to be unsuccessful for a significant improvement in patient-centred care. We continued our research by studying the effect of a more extended intervention strategy within a large randomized controlled trial. Again, on the entire level of patient-centredness, our intervention was not successful in improving care experiences for all women. However, we did find some interesting results within subgroups of patients.

What does these results mean? Did we fail in improving the patient-centredness of fertility care or did we just find some important clues on how patients' experiences with care could be optimally improved in the future? A more in-depth discussion regarding patient-centred care and both the positive and negative

results of our studies is obviously needed to provide some recommendations on how to proceed, both in daily clinical care and in research. We will start with our ideas on the concept of patient-centredness in itself and how to put the 'science' of studying patient-centred care in relation to other outcome measures in healthcare.

Alpha and beta sciences

According to the Institute of Medicine, quality of healthcare should include effective, safe, efficient, timely, equal and patient-centred care.¹ It is interesting to point out how patient-centredness differs on many aspects from the other dimensions of quality of care. For example, healthcare providers will agree on the importance of effective, safe and timely healthcare for their patients.⁶ This is however more complicated for patient-centredness, as most healthcare providers agree that patient-centredness is important, but disagree on *why* it is important. Duggan *et al.* pointed out that some professionals consider patient-centredness only as a good thing if it has good consequences, such as improved patient outcomes or decreased costs.⁷ However, others believe that providing patient-centredness is important because it is morally good and possess some intrinsic property of 'rightness'.⁷ Finally, a third group attaches importance on solely the development of patient-centred attitudes, which would eventually influence their behaviour toward their patients.⁷ Obviously, professionals' visions and motives towards patient-centred care vary, distinguishing patient-centredness from other dimensions of quality of care.

This can also be illustrated when focusing on the measurement and improvement of different quality of care dimensions. For example, measuring the effectiveness and safety of fertility care might be relatively simple by calculating pregnancy rates per clinic and determining the number of complications during IVF treatment, respectively.^{8,9} Also the efficiency of an intervention to improve pregnancy rates in fertility care could easily be studied by means of a cost-effectiveness study in a large patient sample. Subsequently, professionals, managers and policy makers can use these evidence-based results to optimize treatments or develop guidelines. From this point of view, the science considering the majority of quality of care dimensions can be seen as 'beta science', since the outcome measures are merely independent of the context. This does clearly not count for patient-centredness. Patient-centredness is defined by the Institute of Medicine as 'care that is respectful of and responsive to individual patient preferences and needs and that is guided by patient values'.¹ This definition already implies the need for another approach when measuring or improving this outcome measure as it should take the wishes, needs and preferences of patients into account, which obviously differs among them. Objectively measuring mean patient-centredness

scores of a clinic might therefore be considered a *contradiction in terminis*.¹⁰ Accordingly, we can see the science of patient-centred healthcare as an 'alpha science', since the outcome measurements are highly dependent of the individual patient's context. This can be underlined with findings from the general literature, showing relations between patient-centredness or positive care experiences and patient characteristics such as gender, age, race, and marital status.¹¹⁻¹³ Furthermore, we illustrated in the first chapters of this thesis that also in fertility care patient-centredness could be considered an alpha science as it was associated with different patient-related outcomes, such as patients' psychosocial well-being and gender. To get a better understanding of the context of patient-centred care, we will take a closer look at these chapters and relate the results to the literature to put it in a broader perspective.

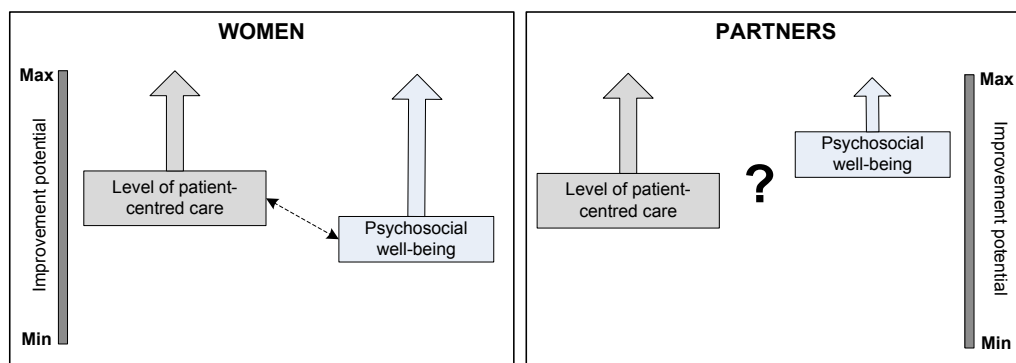
Patient-centred fertility care and its context

In chapter 2, we found significant associations between patient-centred fertility care and patients' QoL and levels of distress. This touches on the results of studies within other healthcare areas, showing for example higher satisfaction rates when patients needed less psychosocial support.^{14,15} Also significant associations between more patient-centred care experiences, improved well-being and higher levels of QoL are described.^{16,17} This might imply that paying attention to patients' psychosocial well-being could improve the level of patient-centred care. However, the cross-sectional study designs limit us to draw conclusions on the actual direction of this association. More research on this subject is needed, but that will not be enough. Within the setting of fertility care, where patients are represented by both the woman and her partner, information regarding both members of the infertile couple is needed. Results from this thesis showed that infertile women and their partners report comparable experiences with patient-centred care. This relates to the results of a Danish study, showing no differences between infertile women and partners on their evaluation of different patient-centred services (e.g. decision making, personal interest of the doctor).¹⁸ These similarities between both members of the infertile couple can be considered a positive finding as it has been shown that a couple's agreement increases the ability to manage stressful events, such as the experience of being infertile.¹⁹ However, we detected some important differences between women and partners as well, as women had significantly lower levels of QoL and more risk factors for emotional problems during treatment than their partners. Different studies in fertility care confirm this²⁰⁻²³ and also within other healthcare areas (i.e. paediatric care and oncology), more stressors and higher levels of psychological distress were shown among female compared to male patients.²⁴⁻²⁶

When aiming at the improvement of patient-centred care, both in fertility care and in other healthcare areas, we have to keep these study results in mind. We therefore composed a figure that integrates these results and consequently points out how healthcare professionals should take the relevant context of their patients into account. Moreover, it shows which information is still lacking, stressing out the focus for further research.

Figure 1.

Interactions between patient-centred care and psychosocial well-being for women and partners



The relation between patients' experiences with patient-centred care and patients' psychosocial well-being are pointed out for both women and partners here. The large arrows represent the improvement on the different outcome measures that could maximally be achieved.

Considering the left side of the figure (i.e. the situation for women), the dotted double arrow between 'level of patient-centred care' and 'psychosocial well-being' illustrates our limited knowledge about the direction between these outcome measures. First, more patient-centred care could relate to more psychosocial well-being for women. If this is true, it should strengthen professionals' motivation to improve their clinic's level of patient-centredness as it would, for example, reduce women's effects of treatment on their mood or decrease feelings of isolation. However, the association could also be explained the other way around (i.e. better psychosocial well-being relates to more experienced patient-centredness). This stresses out the importance of integrating QoL aspects into care delivery and paying attention to anxiety and depression symptoms to improve patient-centredness of care. Also a more complex situation among these outcome measures is possible in which both outcomes interact with each other or even with another, still unknown, outcome measure. For example, paying attention to anxiety and depression would improve patients' experiences with patient-centred care, which in turn improves other aspects of patients' psychosocial

well-being, such as their relational or social status. Until more information is known regarding the actual direction of the association, we advise professionals to pay more attention to women's psychosocial status in daily clinical care, as improvement regarding their psychosocial status is needed²⁷ and it might help them in improving their clinic's level of patient-centred care as well. Instruments like the FertiQoL, HADS and SCREENIVF questionnaires could be used to identify women at risk of emotional problems during or after treatment.²⁸⁻³¹ Consultation of a psychologist or social worker could be helpful for these patients to cope with their psychologically difficult situation. However, paying attention to the psychosocial well-being of a patient could also be considered as a continuum process which is not only set aside for psychologists or social workers. Also physicians and nurses should provide emotional support to their patients in daily clinical practice by discussing for example patients' relational or social situation or just by showing some personal interest in a patient's situation.^{4,27,32}

According to the right side of figure 1, focusing on partners' psychosocial well-being in order to improve their experiences with patient-centred care might seem less beneficial. First, because an association between patient-centred care and psychosocial well-being was never studied or evaluated at all. Second, the psychosocial well-being of partners seems already rather good and the maximum improvement potential on this outcome measure might therefore be limited. Some criticism regarding this statement is however needed. Since we used questionnaires that were only validated in women^{28,29}, we might have missed issues that are relevant to partners. For example, a questionnaire for men experiencing infertility due to a male factor consisted of many questions about 'sexual relationship' and 'gender identity', while these items are only seldom part of a women's questionnaire.³³ Also in the area of urology, it was shown that a questionnaire for men suffering from erectile dysfunction consisted of many different items than the questionnaire for the female partners of these men.³⁴ These clear differences might be due to the use of different coping strategies of men and women.^{35,36} In fertility care, women appeared to use greater amounts of confrontative coping, accepting responsibility and avoidance coping. In contrast, partners tend to use coping techniques, such as distancing, self-controlling and planful problem-solving.^{35,36} Moreover, van Dongen *et al.* showed that partners that were indicated as at risk for emotional problems during treatment felt less need for professional psychosocial support than women³⁷, possibly because they did not recognize themselves into the questionnaire items. This underlines the importance of studying topics that are relevant for partners in fertility care and incorporate them within a new questionnaire. A next step would be to explore the relationship between the results of this questionnaire and patient-centredness, illustrating the need to focus on partners' psychosocial well-being as well in order

to improve their experiences with patient-centredness of care.

The mainstream patient vs. the individual patient

We already considered the study of patient-centredness as an alpha science as it very much depended on patients' emotional and psychosocial context. In daily care and research however, it seems like we still consider patient-centredness as an independent beta science since we use fixed-item instruments to measure concepts such as patient satisfaction, patients' experiences with care and / or patient-centredness.^{5,18,38,39} These fixed instruments reflect the importance of the mainstream patient while the experiences of the individual patient are neglected.¹⁰ Consequently, fixed-item instruments have a reduced responsiveness when it is used in healthcare settings with a wide inter-individual variability in patients' preferences and needs.⁴⁰ Fertility care can be considered such a healthcare setting as the often lengthy diagnostic and treatment periods will alter the needs and wishes of the individual patient over time.^{27,41} For instance, when infertile patients visit the clinic for the first time, they want to fulfil their child wish, but also receive as much information as possible and have the same doctor every meeting. On the contrary, patients being under treatment for already one or two years, might want to receive more emotional or psychosocial support as well, as they feel socially isolated or have feelings of anxiety or depression due to the burden of infertility and its treatment. This stresses out the need for more focus on at least relevant subgroups of patients (e.g. patients who are in similar treatment phases, or have similar feeling of anxiety or depression) instead of concentrating on the entire infertile patient group.

Within our study, we tried to take this into account by using the PCQ-Infertility questionnaire, which was based on the input of many patients from different focus groups across the Netherlands. Therefore, the PCQ-Infertility represents the most important wishes, preferences and needs of Dutch infertile patients throughout their entire treatment course.⁵ Moreover, this questionnaire was able to discriminate between clinics as has been shown in the validation study of the PCQ-Infertility.⁵ We can therefore state that individualization at the clinic level was reached in our study as patient-centredness levels were measured in 32 Dutch clinics and all intervention clinics worked on their own, 'individual' action points that needed improvement. However, as we stated before, patient-centredness is about the experiences and expectations of the individual *patient* instead of the individual *clinic*. Because the PCQ-Infertility is still a fixed-item instrument, it might lack the ability to take into account *all* wishes and preferences of the individual patient. This might be an important reason for why we did not find a significant effect in our entire study group. This is even strengthened by the fact that we did find significant improvements among specific patient groups, namely

younger, less experienced patients, and those who received complementary and alternative medicine. Possibly, our outcome measures and interventions were adjusted to the preferences and wishes of these subgroups. For the other patients however, none or only a few of the aspects that their clinics focused on were in line with their own preferences or expectations. Any improvement on these items could consequently be lost in the overall 'noise' of the other items.⁴² This is in line with the literature, showing that patients are biased by their expectations and previous experiences with care, reducing the effect of interventions aiming at care improvement.^{43,44} More individualized strategies might therefore be needed.

Improving patient-centred care, the next step!

The previous paragraph illustrated that we should move away from studying entire patient groups and aim at relevant subgroups of patients. But maybe we should go even one step further and focus on the most optimal subgroup of patients, i.e. the individual patient. For daily clinical care, this means that healthcare professionals have to concentrate on outcomes and goals that are important to one particular man or woman.⁴⁰ In current healthcare, mainly standard or fixed outcomes are evaluated by professionals and patients' individual expectations for treatment outcomes are largely ignored.^{45,46} Unmet expectations however, might result in treatment dissatisfaction and increase patients' discontinuation of treatment.^{47,48} This partly joins the results of our prospective longitudinal study where more focus on specific domains of patient-centredness was related to treatment dropout. Again however, this only counted for specific patient groups, underlining the need for a more personalized approach in fertility care.

An instrument that can be used to measure personalized patient goals is Goal Attainment Scaling (GAS).^{40,42,45,49-51} GAS consists of a multistep approach that is centred on the communication and interaction between the patient and healthcare provider. GAS starts with the composition of a care and treatment plan that is jointly developed by the professional and the patient and includes goals that are relevant for this individual patient.⁴⁹ For example, the possibility to combine the fertility treatments with a fulltime job, or involving both members of the couple most optimally in the decision making process. Subsequently, patients indicate the importance of the various goals and discuss the expected outcome levels with their healthcare provider. This opens a dialogue and provides an opportunity to eliminate unrealistic goals, address misinformation, and possibly reset patients' expectations for treatment.⁴⁹ Next, the joint care and treatment plan can be used to maintain and reinforce the partnership between patient and professional by evaluating the plan regularly and adjusting it if necessary.⁵⁰

The use of GAS has never been studied in a fertility care setting, but stimulating results have been found within other healthcare areas, such as urology, cardiology and neurology.^{42,45,50} For example, the implementation of GAS was associated with reduced hospital stay, preserved ADL and improved communication among patients and professionals.⁵⁰ Also Velikova *et al.* found that when physicians were provided with the individual wishes and preferences of their patients, the discussion between patient and physician was more in-depth and focused on items that were relevant for the patient, without increasing the overall amount of time.⁵² Moreover, patients reported better emotional functioning⁵² and last but not least, GAS measures were found to be more responsive to change than measures commonly used to evaluate the effectiveness of specialized interventions.⁵¹ This seems especially valuable when aiming at and estimating the improvement of patient-centred care. GAS could therefore be a suitable tool within the area of fertility care as well, and consequently improve infertile patients' experiences with care, although this hypothesis should be studied first.

Now that we have mentioned GAS as a potential new tool in fertility care, it might seem like we focused on the wrong outcome measure or did not use the most optimal intervention to improve the patient-centredness of fertility care in this thesis, but that is not the case. We have to keep in mind that information regarding the improvement of patient-centredness was scarce at the start of our study⁵³⁻⁵⁶, especially in the area of fertility care.^{57,58} Because our intervention integrated the input of physicians, fertility nurses and quality officers and even included (former) infertile patients in different phases, we already strived for a rather individualized approach compared to previous studies. Given the stimulating results of our study on one domain of patient-centredness and on several subgroups of patients, both the multifaceted improvement strategy and the PCQ-Infertility questionnaire can still be of high value in daily practice. However, we should be aware that we might oversee important elements at the individual patient level. A unique combination of a patient-centred approach at both the clinic and the individual level is therefore needed. This was also suggested by Khullar *et al.* where GAS appeared to be more suited to complement rather than to replace established outcome measures, since both measures have their own, unique advantages and disadvantages.⁴⁶ We therefore suggest clinics to measure their clinics' levels of patient-centredness regularly by means of the PCQ-Infertility questionnaire. In the absence of a more individualized questionnaire, the PCQ-Infertility can be considered the most optimal tool to measure patients' experiences with fertility care. Next, feedback can be provided through a report and an educational meeting, providing insight for professionals into the need for more general improvement projects in their clinics. For example, keeping their information provision up to date or improving the accessibility of their fertility care department by phone

or e-mail. This cycle needs to be repeated at regular intervals to keep clinics' general status of patient-centredness up to date.⁵⁹ Evidence regarding the most optimal length of these interval is scarce, but we suggests to repeat the cycle of auditing, feedback, and defining concrete action points for improvement every one or two years. As an additional step, GAS could be incorporated in daily care by listening to patients' personal wishes and needs and come up with a shared treatment plan. In future research we should study the most optimal combination of improving patient-centredness at both the clinic and the individual level.

Designing future research

One last question regarding the measurement and improvement of patient-centred care is still unanswered. It was already mentioned that more research is needed regarding the improvement of patient-centred care, but how the most optimal design of such a study should look like should be discussed. In the second part of this thesis, we performed a mixed method study to determine the effect of audit and feedback on patient-centred fertility care and simultaneously explore professionals' views regarding the improvement of patient-centred care. A comprehensive study design thus which can be considered as an optimal design for a complex outcome measure such as patient-centredness. When it turned out that solely audit and feedback was unsuccessful we tested the effect of the more extended, multifaceted improvement strategy within a cluster-randomized controlled trial (RCT). RCTs are widely viewed to provide the greatest value to assess the effects of interventions and are therefore hailed as the gold standard. Nevertheless, they may not always be feasible or adequate for evaluating the effectiveness of care interventions that include more complex outcome measures or interventions.⁶⁰⁻⁶² It is therefore debatable whether a change in patients' personal experiences with care can be captured within a randomized controlled trial. More experimental, qualitative or pragmatic study designs may for example be more suitable.⁶³⁻⁶⁵ For evaluating patient-centred care, 'story telling' could even be used as the most distinct form of qualitative research.^{66,67} Although these study designs are sometimes labelled as 'weak', we would recommend considering such a study design when studying complex outcome measures, such as patient-centredness. In the end, when applying it in a correct setting, the results of these studies may really show us how to improve patients' experiences with patient-centred fertility care.

Implications for practice and further research

In this chapter, we already mentioned several implications for daily practice and research while discussing the results of our studies. However, we feel that applying our study results is highly important and we therefore summarize the

most important implications for patients, healthcare providers, policy makers and future research here.

Patients

This thesis is not only *about* the patient, but also *for* the patient. Implications for infertile patients should therefore not be missing. Our thesis showed that patients have an important voice when it comes to their wishes and preferences in fertility care. Importantly, this should not only be applied within research settings, but especially in daily clinical practice. We therefore encourage patients to let professionals hear their voice and feel responsible about their own role in increasing the patient-centredness of care. This can be practiced at the secretary desk, in the doctor's room, but also for example via patients' organizations. Showing your own wishes and expectations of a particular treatment opens the discussion with the healthcare provider and will just improve the relation between patient and professional. Only by an optimal commitment of both the infertile patient and the healthcare provider, we can perfectly 'work together' to a patient-centred approach in fertility care, just as mentioned by the patient in the prologue of this thesis.

Healthcare providers

The different chapters in this thesis underlined the importance of patient-centredness in fertility care, which should be an eye-opener for healthcare providers in fertility care. More focus on patient-centred elements in daily clinical care is needed, but being aware of professionals' own strengths and shortcomings is maybe even more important. Our mixed-method study showed that professionals are in general aware of the value of patient-centred care, but knowledge about their own performance and how to translate this into improvement projects is difficult. Professionals should therefore measure their clinic's levels of patient-centredness regularly and discuss their results within the entire team, particularly with the help of a quality officer or another professional apart from the fertility team. These meetings will be motivating for the entire team to keep their focus on the patient and provide care that is most important to them. Moreover, healthcare providers should keep in mind the preferences and needs of the individual patient, by discussing patients' expectations and wishes at the start of their treatment. The formulated treatment plan with individual patient goals can subsequently be used as an optimal guidance throughout the entire treatment process. Only when professionals are more open-minded towards this individualized approach in healthcare we can really provide patient-centred, and thus high quality healthcare.

Policy makers

Also for managers and other policy makers, the results of the studies in this thesis should stress out the importance of patient-centredness in fertility care. Especially the chapter about the monetary value of patient-centred care seems interesting for policy makers as the results of this study suggest the need for a debate about the payment for patient-centred care. Patients were willing to pay a considerable amount of money next to their insurance premium in order to be treated in a clinic providing more patient-centred care. Policy makers should therefore explore the introduction of additional copayments for patient-centred clinics. This would not only be in line with the preferences of infertile patients, according to our study, but could also enhance market forces and competition among clinics. From the perspective of the policy maker, this could be a new, challenging policy for the future.

Future research

The results of the first part of this thesis have completed a few pieces of the large puzzle of patient-centredness and its context. However, more research on this subject is still needed. First, the actual direction of the association between patient-centredness and patients' psycho-social well-being should be further studied to make clear how for example QoL, depression and anxiety should be taken into account when improving patient-centredness of fertility care. Second, we have given a voice to the partner of the infertile couple, but information regarding partners' preferences and needs in fertility care is still limited. Therefore, more qualitative or mixed-method research is needed to study the preferences and needs of partners regarding patient-centred fertility care. Considering the improvement of patient-centred care, the use of an individualized approach such as GAS could complement a multifaceted improvement strategy aiming at clinics' levels of patient-centredness. We should learn from other healthcare areas on how GAS could be optimally studied and implemented in daily care. Moreover, we should keep in mind that a randomized trial is not always the most optimal study design to study outcome measures at an individual patient level. For example, large cohort studies, qualitative, mixed method or experimental designs are recommended to use in the future.

Final conclusion

In this thesis, we have shown that healthcare needs to be more patient-centred and improvement strategies are within our reach. Because patient-centredness is a multidimensional and complex concept it must be 'treated' accordingly. We should therefore consider patients' individual context when measuring the patient-centredness of healthcare. Furthermore, strategies for improvement should not only aim at the clinic level, but incorporate patients' personal views towards patient-centred care as well by listening to their individual expectations, wishes and needs throughout the entire treatment process. Obviously, an ambitious but important journey is ahead of us and staying on our route towards more patient-centred healthcare could be the most challenging task for the future!

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CHAPTER 12

SUMMARY

Summary

Chapter 1

The rationale for this thesis is described in this first chapter, the **General Introduction**. Paying attention to patient-centredness of care is gaining more and more attention in daily practice nowadays. According to the Institute of Medicine, patient-centredness is defined as 'care that takes into account patients' preferences and needs and is guided by patients' values'. Especially patients suffering from infertility could benefit from patient-centred care, as fertility treatments are a physical and psychological burden to them. Previous studies have shown that the level of patient-centred fertility care varies considerably among clinics and improvement is needed. However, no golden standard is available on how to promote and improve patient-centred fertility care. The different studies in this thesis will contribute to the development of such a standard

PART I

In the first part of this thesis, we put patient-centred fertility care in a broader perspective and created a proper basis to come to an optimal intervention for improving patient-centred fertility care. This part consists of five chapters.

Chapter 2

Providing patient-centred care by tailoring care to patients' individual needs and preferences could remove some of the emotional burden of infertility (e.g. quality of life and distress). This might also be true the other way around: the patient's well-being could influence their experiences with care, because of the high emotional impact of being infertile. To gain more insight into these possible associations we performed a cross-sectional study in which we studied the relationship between the level of patient-centred care, measured by the PCQ-Infertility, and their well-being, measured by the FertiQoL and HADS questionnaires. From 29 Dutch fertility clinics, 427 non-pregnant patients filled out the Patient-Centredness Questionnaire-Infertility (PCQ-Infertility), FertiQoL and HADS (response rate 74%). Multilevel linear regression analysis showed significant associations between the PCQ total scale, the FertiQoL total scale ($B=0.250$) and the HADS subscales ($B=-0.215$ for 'Anxiety'; $B=-0.180$ for 'Depression'). Thirteen percent of the variance in patient-centred care could be explained by their perceived quality of life, twelve percent by their level of anxiety and ten percent by their

level of depression. The inter-relationship between patient-centred fertility care and their well-being implies that paying attention to a patients' well-being could lead to positive care experiences and improved patient-centredness of care. However, because of the cross-sectional study design, the results in this chapter could also mean that improved patients' experiences could lead to better quality of life and less anxiety and depression among infertile patients. Future research should focus on identifying causal relationships among these variables.

Chapter 3

Infertility seems to be the perfect example of a condition involving both a woman and her partner, both having their own wishes, needs and expectation regarding treatment. Therefore, it is remarkable that available fertility care research typically includes infertile couples as a whole or women alone, while partners seems to be a forgotten party. Especially if we aim at the improvement of patient-centred fertility care, we should focus on both members of the infertile couple. Therefore, we performed a cross-sectional study within 32 Dutch fertility clinics to assess possible differences in experiences with patient-centred care between women and their partners. We selected a total of 1620 infertile women and their partners and measured the level of patient-centred care with the PCQ-Infertility. We used multilevel multivariate linear regression analysis to investigate intra-couple experiences and to account for significantly related background characteristics (e.g. age and treatment type). After excluding pregnant couples, questionnaires from 696 women (response rate 58%) and 520 partners (response rate 41%) could be analyzed. No significant differences in PCQ-Infertility total scores were found between women and their partners. The partners scored significantly higher on the subscales 'Respect for patients values' and 'Staff's competence' compared to their women. These results implicate that patient' experiences with fertility care are only slightly different between women and their partners, which is valuable information in the process of improving patient-centred fertility care.

Chapter 4

It is already known that the psychological impact of infertility negatively affects patients' quality of life (QoL). However, it is unclear if differences in QoL and emotional status exist between infertile women and their partners. Moreover, research mainly focuses on generic instruments to measure infertile patients' QoL, while these instruments do not represent all the unique problems of patients experiencing infertility. The main aim of this study was therefore to explore possible differences in QoL and well-being between women and their partners, using the disease-specific FertiQoL and SCREENIVF questionnaires. In this cross-sectional study, we included 1620 infertile women and their partners under treatment in

one of the 32 participating clinics. We used the FertiQoL questionnaire to measure patients' QoL, and risk factors for emotional problems during and after treatment were measured with the SCREENIVF questionnaire. To determine possible intra-couple differences in FertiQoL and SCREENIVF scores between women and their partners, we performed multilevel linear regression analyses in which we included twelve relevant patient characteristics. Questionnaires from 696 women (58%) and 520 partners (41%) could be analysed. Women scored significantly lower on the FertiQoL total scores and three of the FertiQoL subscales ('Emotional', 'Mind-Body' and 'Social') than their partners, indicating lower QoL. Scores on the SCREENIVF questionnaire were significantly higher for women, indicating that women are more at risk for developing emotional problems during and after fertility treatment than their partners. Moreover, there were differences in the kind of risk factors. This indicates that both members of the infertile couple are vulnerable to different sources of psychological stress, which underlines the importance of identifying risk factors for emotional problems for both members of the couple separately. Only then, infertile women and partners can receive the tailored psychosocial support they need.

Chapter 5

In fertility care, a significant proportion of patients does not achieve pregnancy because they discontinue treatment prematurely. This is often due to the physical or psychological burden they encounter. Identifying prognostic factors for dropping out treatment could be useful to develop interventions targeting exactly those burdensome aspects of treatment. Previous studies regarding this subject show inconsistent results, which could be explained by their poor methodological quality or their focus on factors at the treatment and patient level, while clinic factors have not been paid attention to. Clinic factors could include standard characteristics, such as the size of a clinic, but also patients' experiences with patient-centred care can be considered a clinic factor. The aim of this study was to explore prospectively to what extent clinic factors, including the level of patient-centred care, can be used as a predictor for dropout in fertility care. At T0, 693 infertile women completed a questionnaire about their experiences with patient-centred fertility care (PCQ-Infertility). Meanwhile, a professionals' questionnaire was used to gather additional clinic characteristics. After one year (T1), 434 patients (response 81.3%) completed a questionnaire about their current status in fertility care, including their main reason for discontinuation, if applicable. Of these women, 153 women (35.2%) continued treatment and 76 women (17.5%) dropped out. The remaining patients were excluded from analysis, for example because they achieved pregnancy. Binary logistic regression analyses showed that either levels of patient-centredness nor the additional clinic characteristics did significantly differ between dropouts and compliers. However, patients who

received non-ART treatments before they dropped out had significantly lower scores on the PCQ-Infertility subscale 'Respect for patients' values' than patients who continued their treatment. Patients receiving ART treatments and subsequently dropped out treatment, had higher scores on the PCQ-Infertility subscale 'Patient involvement'. These results suggest that most clinic factors are not related to dropout and seem therefore no optimal predictor for dropout. However, clinic factors might be of use when predicting dropout for specific patient groups.

Chapter 6

In this chapter, we studied the importance of patient-centredness in current healthcare by determining its monetary value. Therefore, we performed a Discrete Choice Experiment (DCE) to assess what both patients and health insurers were willing to pay for more patient-centred fertility care. We included infertile patients from ten Dutch fertility clinics and healthcare purchasers from the five largest Dutch healthcare insurer companies. All participants received a DCE questionnaire, consisting of choice sets representing hypothetical but realistic fertility clinics that differed on the following attributes: pregnancy rate, patient-centredness (i.e. information provision, patient involvement, and continuity of care) and out-of-pocket costs. All attributes were divided into three levels covering a realistic range. With logistic regression analysis, we determined the attributes' relative importance and calculated a willingness-to-pay for more patient-centred care for both patients and health insurers and related this to the willingness-to-pay for higher pregnancy rates. In total, 521 patients (52.5%) and 45 healthcare purchasers (53.6%) completed the DCE questionnaire. All five attributes were significantly important to patients' and healthcare insurers' choice of a fertility clinic. However, patients and insurers differed in the value they placed on different attributes. In particular, patients were willing to pay a medium amount of €463 for a relevant one-step increase in patient-centred care and €107 for a one percent increase in pregnancy rates. Healthcare insurers' valuations were lower: €191 for more patient-centred care and €60 for one percent increase pregnancy rates. These results reflect the importance of patient-centredness for infertile patients and should increase professionals' urge to improve their clinics' levels of patient-centred care. Moreover, as patients were willing-to-pay a considerable amount of money for a clinic offering more patient-centred care, there may be a willingness to allow for optional copayment for patient-centred aspects of care.

PART II

The second part of this thesis contains three chapters about the improvement of patient-centred fertility care.

Chapter 7

Beside traditional outcomes as safety and (cost-)effectiveness the Institute of Medicine calls patient-centredness as an independent outcome indicator to evaluate quality of healthcare. Providing patient-centred care is important because patients feel to be heard in their ideas and concerns. This is also true in the area of fertility care where patients suffer from a high physical and physiological burden. How care can become optimally improved in patient-centredness is unknown, but audit and feedback are often key components of quality improvement projects. Therefore, we performed a mixed methods study to determine the effect of audit and feedback on the level of patient-centredness in fertility care, and getting more in-depth understanding of professionals' view on the improvement of patient-centred care. In the quantitative part, we first measured the level of patient-centred care in 15 Dutch fertility clinics using the PCQ-Infertility (T0). Then, feedback was provided to the clinics by means of a personalized feedback report. After two years, the level of patient-centred care was measured again (T1) and we used multilevel linear regression analysis to determine possible differences in the level of patient-centredness between T0 and T1. In the meanwhile, we performed semi-structured in depth interviews with 15 fertility care professionals to explore their views on improving patient-centred care. Our results showed that the overall levels of patient-centredness did not differ between T0 and T1, indicating that audit and feedback solely is not enough to improve the level of patient-centred fertility care. The results of our qualitative research indicated that professionals' urge to change and their ability to translate feedback were suboptimal to achieve professionals' behavior change. Consequently, this appeared to be the key issues when aiming at the improvement of patient-centred fertility care.

Chapter 8

The previous study has provided us with some important clues on how an optimal improvement strategy for patient-centred fertility care should look like. Based on these results and the corresponding literature, we designed a study to determine the effects of a multifaceted intervention strategy. In this chapter we presented

the study protocol. In a cluster-randomized trial in 32 Dutch fertility clinics, the effects of a multifaceted approach were determined on the level of patient-centredness, as measured with the PCQ-Infertility. Also the effect on patients' QoL (FertiQoL) and levels of distress (SCREENIVF) were studied. We collected potential determinants of a change in patient-centredness, patients' QoL and levels of distress by an addendum to the patients' questionnaire and a professionals' questionnaire. Then, a total of 16 clinics were randomized to the multifaceted approach, consisting of three different elements. First, all clinics received a personalized feedback report with their own results on the questionnaires, presented in relation to all 32 participating clinics. Subsequently, the content of the feedback report was discussed per clinic in an Education Outreach Visit with the entire professional team. This resulted in an action plan on how to improve their level of patient-centred fertility care. Finally, patient-mediated interventions were offered to all clinics to enhance their patient-professional communication, such as organizing focus groups. The 16 clinics in the control group provided care as usual. After one year, we measured levels of patient-centred care, patients' QoL and distress again. The study expected to yield important new evidence about the effects of a multifaceted approach on levels of patient-centredness, patients' QoL and distress in fertility care. By having knowledge of these results, patient-centred care, and thus quality of healthcare, can be improved. Moreover, the results of this study could be useful for similar initiatives to improve the quality of care delivery.

Chapter 9

In chapter 9, we studied the effect of the multifaceted approach on the total and subscale scores of the PCQ-Infertility using multilevel multivariate linear regression analysis. We also determined the influence of different patient characteristics on the effect of our intervention by adding significant interaction terms to our model concerning the PCQ-Infertility total score. Finally, we calculated the costs of the multifaceted approach from a societal perspective. A total of 696 patients (response 58.4%) from 32 Dutch fertility clinics were eligible for analysis at baseline measurement. One year later, at the after measurement, we analysed the data of 730 patients (response 60.4%). The total level of patient-centredness did not significantly differ between the intervention and the control group at after measurement, when adjusted for baseline scores and relevant case-mix adjusters (e.g. age and treatment type). On one of the seven PCQ-Infertility subscales (i.e. 'Continuity of care'), scores were significantly higher in the intervention group compared to the control group ($B=0.20$). Moreover, patients in the intervention group had significantly better experiences with fertility care than patients in the control group when they were under treatment for less than one year, when patients were younger than 36 years and when they used

complementary and alternative medicine. Total yearly costs for the multifaceted approach were €64.628, which was €13 per patient per clinic (range €2-€28). Additional healthcare consumption and productivity losses did not significantly differ between the intervention and control group during after measurement. This study showed that an intervention including patient-mediated feedback and education is not sufficient to improve care experiences for all patients in fertility care. An increase in the level of patient-centred care could however been achieved in specific patient groups. Future research should therefore explore more individualized strategies and outcome measures to improve care for all patients.

Chapter 10

When studying the effect of complex, multifaceted interventions an extensive process evaluation is of high importance. Process evaluations are not interested in a study's success or lack of success, but take a look into the 'black box' of the intervention to see what actually happened. Therefore, they can be helpful in the interpretation of study results. In chapter 10, we performed a process evaluation of our RCT to evaluate patients' and professionals' experiences with our study. Moreover, we studied the relation between the improvement of patient-centred care and clinics' intensity on the multifaceted strategy and collected determinants at the clinic level of an improvement in patient-centred care. We used different questionnaires to collect our data, showing that both patients and professionals were mainly positive about the different elements of the multifaceted improvement strategy. During the EOVs, clinics came up with a median number of five action points (range: 3-7) to improve their level of patient-centredness. After one year, they had performed 75% of these action points (range: 20-100%), but both the intervention and control clinics did work on many different, additional improvement projects during the study as well. Linear regression analyses showed that the number of executed improvement projects on patient-centred care aspects was not significantly related to patient-centredness improvement. Finally, multivariate regression analyses revealed that improvement in patient-centredness scores (scale: 0-3) was associated with higher levels of patient participation during the EOV ($B=0.051$), higher organizational group culture scores ($B=0.014$), and the absence of structured meetings to discuss all patients within the team ($B=-0.138$). Patient participation, improving teamwork and less fixation on protocols can therefore be considered as key elements to really improve patient-centredness in daily clinical practice.

Chapter 11

This final chapter contains the **General Discussion** and concentrates on the main findings of this thesis. We presented answers to the eight research questions we stated in the General Introduction and discussed these findings by presenting our ideas on the concept of patient-centredness in itself. We debated how studying the patient-centredness of healthcare could be considered as 'alpha science', as it is highly dependent on the individual patient's context. This contrasts with other studies, such as studies investigating efficiency or safety of care. Since these fixed outcome measures are merely independent of the patient's context, we name this 'beta sciences'. As a result, measuring and improving patient-centredness should be approached differently from other quality of care dimensions. First, patients' psychosocial well-being should be taken into account as it had significantly been associated to patient-centred care within many different healthcare areas. In fertility care however, the direction of this association is not clear yet and only studied for women while also the partner is an important member of the infertile couple. More research in this area is obviously needed. Second, levels of patient-centredness are often measured with fixed-item instruments, focusing on the experiences of the mainstream patient, while preferences and expectations of the individual patient are neglected. Therefore, we advise professionals to aim at the improvement of patient-centred fertility care at both the clinic and the individual level. To do so, the PCQ-Infertility questionnaire should be used as a tool to regularly identify elements for improvement for specific clinics. The results of these audits should be discussed within the entire fertility team to come to a collaboratively created improvement plan. Furthermore, healthcare providers have to acknowledge the preferences and needs of the individual patient, by discussing patients' expectations and wishes at the start of their treatment. This should result in a treatment plan that is tailored to the individual patient's needs and goals and should guide the healthcare provider and patient throughout the entire treatment process. Finally, we point out that the use of randomized controlled trials, the gold standard for study designs, is most optimal when studying independent 'beta sciences'. However, when focusing on more context-related 'alpha sciences', such as patient-centredness, mixed-method, qualitative or pragmatic study designs might for example be more suitable. We end the General Discussion with our most important recommendations for patients, healthcare providers, policy makers and future research, showing that an ambitious but important journey is still ahead of us!

CHAPTER 13

NEDERLANDSE SAMENVATTING

Nederlandse samenvatting

Hoofdstuk 1

In dit hoofdstuk, de **Algemene Inleiding**, beschrijven we de aanleiding voor dit proefschrift. Tegenwoordig wordt er meer en meer aandacht besteed aan het leveren van patiëntgerichte zorg. Ook patiënten die onder behandeling zijn vanwege een onvervulde kinderwens hebben baat bij patiëntgerichte zorg, omdat de fertiliteitsbehandelingen zowel lichamelijk als emotioneel erg belastend zijn. Eerdere studies hebben aangetoond dat de mate van patiëntgerichte fertiliteitszorg enorm varieert tussen ziekenhuizen en verbetering is dus meer dan nodig. Er bestaat echter geen gouden standaard hoe patiëntgerichte fertiliteitszorg geleverd en verbeterd moet worden. De studies in dit proefschrift hopen hier een bijdrage aan te kunnen leveren.

DEEL I

Het eerste deel van dit proefschrift beslaat vijf hoofdstukken waarin we de patiëntgerichtheid van de fertiliteitszorg van verschillende kanten bekijken. Dit vormt de basis voor een optimaal verbeterplan voor patiëntgerichte fertiliteitszorg.

Hoofdstuk 2

De emotionele impact van subfertiliteit kan verminderd worden door het afstemmen van de zorg op de behoeften van de individuele patiënt en verbeteren van patiëntervaringen met de zorg. Anders gezegd, de gemoedstoestand van de patiënt kan ook zijn of haar ervaringen met de zorg beïnvloeden, vanwege de grote emotionele impact (verminderde kwaliteit van leven en verhoogde stress) van fertiliteitsproblemen. Om meer inzicht te krijgen in deze mogelijke associaties, voerden we een dwarsdoorsnede onderzoek uit, waarin we de relatie bepalen tussen patiëntervaringen met de zorg, gemeten met de PCQ-Infertility, en hun gemoedstand, gemeten met de FertiQoL en SCREENIVF vragenlijsten. Uit 29 Nederlandse fertiliteitsklinieken vulden 427 niet zwangere vrouwen de drie vragenlijsten in (respons 74%). We pasten multilevel lineaire regressie analyses toe op de data waarin de totale schaal van de PCQ de afhankelijke variabele was. Achtergrondkarakteristieken van de patiënten, de FertiQoL en HADS resultaten beschouwden we als onafhankelijke variabelen. De analyses lieten significante associaties zien tussen de PCQ totale schaal en de FertiQoL totale schaal ($B=0.250$) en de HADS subschalen ($B=-0.125$ voor 'Angst'; $B=-0.180$

voor 'Depressie'). Dertien procent van de variantie in patiëntervaringen kond verklaard worden door hun kwaliteit van leven, twaalf procent door de mate van angst en tien procent door de mate van depressie. De onderlinge relatie tussen patiëntervaringen met de fertiliteitszorg en hun gemoedstoestand impliceert dat door aandacht te besteden aan deze variabelen de ervaringen met de zorg, en de patiëntgerichtheid, verbeterd kunnen worden. Echter, vanwege de opzet van de studie, kunnen de resultaten in dit hoofdstuk ook betekenen dat het verbeteren van de patiëntgerichtheid van de zorg kunnen leiden tot een betere kwaliteit van leven en minder angst en depressie. Toekomstig onderzoek zou zich moeten richten op het identificeren van het causale verband tussen deze variabelen.

Hoofdstuk 3

Subfertiliteit betreft een aandoening die zowel de vrouw als de partner in de relatie aangaat. Vanzelfsprekend zullen beide leden van het subfertiele paar hun eigen ideeën, voorkeuren en ervaringen met de fertiliteitszorg hebben. Het is daarom opvallend te noemen dat fertiliteitsonderzoek hoofdzakelijk het paar als geheel of de vrouw alleen bestudeerd en de partner dus vaak vergeten wordt. Vooral als we de patiëntgerichtheid van de fertiliteitszorg willen verbeteren, is het belangrijk om de voorkeuren van zowel de vrouw als de partner in beeld te hebben. Daarom hebben we een cross-sectionele studie verricht onder 32 Nederlandse fertiliteitsklinieken om mogelijke verschillen in patiëntgerichte ervaringen tussen subfertiele vrouwen en hun partners te bepalen. We vroegen hiervoor aan 1620 vrouwen en hun partners om de PCQ-Infertility vragenlijst in te vullen. Met behulp van multilevel multivariate lineaire regressie analyse konden we vervolgens de verschillen binnen de koppels analyseren en corrigeren voor relevante patiëntkarakteristieken, zoals leeftijd en soort behandeling. Nadat we alle (partners van) zwangere vrouwen hadden geëxcludeerd, analyseerden we de vragenlijsten van 696 vrouwen (response 58%) en 520 partners (respons 42%). We vonden geen verschillen in PCQ-Infertility totaalscores tussen vrouwen en hun partners. Partners scoorden wel significant hoger op de domeinen 'Respect voor patiëntwaarden' en 'Professionaliteit'. Deze resultaten laten zien dat de ervaringen van vrouwen en hun partners met patiëntgerichte zorg voor het overgrote deel met elkaar overeen komen. Dit is belangrijke informatie bij het ontwerpen van een strategie om de patiëntgerichtheid van de fertiliteitszorg te verbeteren.

Hoofdstuk 4

Eerdere studies hebben laten zien dat de psychologische impact van fertiliteitsproblemen een negatief effect hebben op de kwaliteit van leven van subfertiele patiënten. Er is echter geen duidelijkheid in welke mate de kwaliteit

van leven en emotionele status van subfertiele vrouwen en hun partners verschillen. Bovendien gebruiken de meeste studies generieke vragenlijsten om de kwaliteit van leven en emotionele status van patiënten te meten, terwijl deze vragenlijsten niet ingaan op de specifieke problemen waar fertiliteitspatiënten tegenaan lopen. Het doel van deze studie was dan ook om te achterhalen of er verschillen in kwaliteit van leven en welbevinden bestaat tussen subfertiele vrouwen en hun partners, gemeten met de ziektespecifieke FertiQoL en SCREENIVF vragenlijsten. In deze cross-sectionele studie werden 1620 vrouwen en hun partners geïnccludeerd die bij één van de 32 deelnemende ziekenhuizen onder behandeling waren voor hun vruchtbaarheidsprobleem. We gebruikten de FertiQoL vragenlijst om kwaliteit van leven te meten. Met de SCREENIVF vragenlijst werden risicofactoren voor het ontwikkelen van emotionele problemen tijdens of na de behandeling achterhaald. We gebruikten multilevel multivariate lineaire regressie analyse om mogelijke verschillen binnen het subfertiele koppel te achterhalen en corrigeerden voor twaalf relevante patiëntkarakteristieken. In deze studie analyseerden we de vragenlijsten van 696 vrouwen (respons 58%) en 520 partners (respons 41%). Vrouwen hadden significant lagere scores op de FertiQoL totaal score en drie van de vier subschalen van de FertiQoL, wat duidt op een lagere kwaliteit van leven. De scores op de SCREENIVF vragenlijst waren significant hoger voor vrouwen, wat aangeeft dat zij meer risicofactoren hadden voor het ontwikkelen van emotionele problemen tijdens of na de behandelingen. Ook het soort risicofactoren verschildte tussen vrouwen en hun partners. Dit laat zien dat subfertiele vrouwen en hun partners gevoelig zijn voor andere soorten van psychische stress en onderstreept het belang om deze risicofactoren bij beide leden van het paar apart te identificeren. Alleen op deze manier kunnen zij beiden de psychosociale ondersteuning krijgen die ze nodig hebben.

Hoofdstuk 5

In de fertiliteitszorg lukt het veel paren niet om zwanger te worden, omdat zij al voortijdig stoppen met de behandelingen. Vaak is dat, omdat ze het fertiliteitstraject lichamelijk en psychisch te belastend vinden. Het zou daarom goed zijn om prognostische factoren voor deze voortijdige uitval te identificeren, zodat we interventies kunnen ontwikkelen die precies die problemen aanpakken waar paren tegenaan lopen. Eerdere studies die dit onderzochten lieten wisselende resultaten zien, mogelijk vanwege de matige methodologische kwaliteit van veel studies, maar ook omdat de focus vaak alleen op patiënt- of behandelactoren lag, terwijl kliniekfactoren ook een rol kunnen spelen bij voortijdige uitval. Het doel van deze studie was om prospectief te bepalen in welke mate kliniekfactoren, waaronder de mate van patiëntgerichte zorg, als voorspeller voor voortijdige uitval in de fertiliteitszorg gebruikt kunnen worden. Aan het begin van deze studie (T0) vulden 693 subfertiele vrouwen, afkomstig uit 32 verschillende ziekenhuizen,

een vragenlijst in over de patiëntgerichtheid van hun ziekenhuis (PCQ-Infertility). Tegelijkertijd verzamelden we met een vragenlijst voor professionals de overige kliniecfactoren, als mogelijke voorspeller voor voortijdige uitval (bijv. de grootte van een kliniek of de aanwezigheid van een fertiliteitsverpleegkundige). We vervolgden de patiënten één jaar, waarna zij een vragenlijst ontvingen over hun huidige status in de fertiliteitszorg (T1). In geval van voortijdige uitval gaven zij hun meest belangrijke reden daarvoor. Tijdens T1 vulden 434 vrouwen (respons 81.3%) de vragenlijst in. Van deze vrouwen waren er 153 (35.2%) nog onder behandeling en 76 vrouwen (17.5%) waren voortijdig gestopt. Met binaire logistische regressie analyse vonden we dat zowel de patiëntgerichtheid van de zorg als de overige kliniecfactoren niet significant geassocieerd waren met voortijdige uitval. In de groep patiënten die non-invasieve behandelingen ontvingen (bijv. inseminaties), hadden patiënten die voortijdig uitvielen echter een significant lagere (slechtere) score op het domein 'Respect voor patiëntwaarden'. Voor patiënten die invasieve behandelingen ondergingen (bijv. IVF) was de voortijdige uitval juist hoger bij een hogere (betere) score op het domein 'Autonomie'. Deze resultaten suggereren dat de meeste kliniecfactoren niet gerelateerd zijn aan voortijdige uitval in de fertiliteitszorg en daarom geen optimale voorspellers lijken te zijn. Voor bepaalde patiëntgroepen zouden sommige domeinen van patiëntgerichte zorg wellicht wel als voorspeller gebruikt kunnen worden.

Hoofdstuk 6

In dit hoofdstuk bestudeerden we het belang van het leveren van patiëntgerichte zorg door de "financiële waarde" van patiëntgerichtheid vast te stellen. Dit deden we middels een keuze-experiment (zgn. Discrete Choice Experiment) waarbij we voor zowel patiënten als verzekeraars berekenden wat zij willen betalen voor meer patiëntgerichte zorg. Voor deze studie includeerden we 993 subfertiele patiënten uit tien verschillende Nederlandse ziekenhuizen en alle 84 zorginkopers van de vijf grote Nederlandse zorgverzekeraars. Zij ontvingen allen een vragenlijst waarin ze meerdere malen moesten kiezen tussen hypothetische fertiliteitsklinieken die van elkaar verschilden in de volgende kenmerken: zwangerschapskans, patiëntgerichtheid van de kliniek (informatievoorziening, autonomie van de patiënt en continuïteit van de zorg) en extra kosten per cyclus. Aan patiënten vroegen we in welke kliniek zij behandeld zouden willen worden en aan verzekeraars in welke kliniek zij de zorg zouden inkopen. In totaal namen 521 patiënten (52.5%) en 45 zorginkopers (53.6%) deel aan de studie. De resultaten van de logistische regressie analyse lieten zien dat alle vijf de kenmerken voor zowel patiënten als zorginkopers significant van belang waren bij hun keuze voor een kliniek. Voor één stap verbetering in patiëntgerichte zorg waren patiënten bereid €463 per cyclus te betalen, terwijl ze voor 1% hogere zwangerschapskans €107 over hadden. Voor zorgverzekeraars was dit €191 voor meer patiëntgerichte zorg en €60

voor 1% hogere zwangerschapskans. Deze resultaten benadrukken het belang van patiëntgerichtheid in de huidige gezondheidszorg en verhogen mogelijk de motivatie voor zorgprofessionals om de patiëntgerichtheid van hun kliniek verder te verbeteren. Bovendien zouden deze resultaten een aanzet kunnen zijn voor een eigen bijdrage voor patiëntgerichte zorg, aangezien patiënten blijkbaar een behoorlijk bedrag zouden willen betalen voor een kliniek die meer patiëntgericht werkt.

DEEL II

Het tweede deel van dit proefschrift gaat over het verbeteren van patiëntgerichte fertiliteitszorg. Dit deel bestaat uit drie hoofdstukken.

Hoofdstuk 7

In de literatuur wordt naast traditionele uitkomstmaten als (kosten)effectiviteit en veiligheid ook patiëntgerichtheid als een belangrijke en onafhankelijke uitkomstmaat genoemd om kwaliteit van zorg te meten. Het is belangrijk om patiëntgerichte zorg te leveren, zodat patiënten zich gehoord en begrepen voelen in hun eigen normen en waarden. Dit geldt zeker ook voor subfertiele patiënten, aangezien de fertiliteitszorg zich kenmerkt door een hoge lichamelijke en psychische belasting en veel voortijdige uitval, zoals in de vorige hoofdstukken beschreven. Hoe we de patiëntgerichtheid van de fertiliteitszorg echter optimaal kunnen verbeteren is onbekend, alhoewel audit en feedback vaak ingezet worden als hulpmiddelen voor het verbeteren van de zorg. Wij voerden daarom een *mixed-methods* onderzoek uit, waarbij we het effect van audit en feedback op de patiëntgerichtheid van de Nederlandse fertiliteitszorg onderzochten. Daarnaast probeerden we te achterhalen hoe zorgprofessionals denken over het leveren en verbeteren van patiëntgerichte fertiliteitszorg. In het kwantitatieve deel van deze studie werd allereerst de mate van patiëntgerichte zorg in 15 ziekenhuizen gemeten met behulp van de PCQ-Infertility vragenlijst (T0). Daarna ontvingen de klinieken een feedback rapport met de resultaten van deze meting. Na twee jaar werd de mate van patiëntgerichte zorg opnieuw gemeten (T1) en vergeleken we met multilevel lineaire regressie analyse het verschil in patiëntgerichtheid tussen T0 en T1. Gedurende die twee jaar interviewden we 15 professionals uit de fertiliteit zorg en achterhaalden hun ideeën over het verbeteren van patiëntgerichte zorg. De uitkomsten van deze interviews analyseerden we met thematische inhoudsanalyse waarna we de uitspraken indeelden in de vier stappen voor gedragsverandering volgens Hibbard: bewustzijn, kennis, houding en gedrag.

Onze resultaten toonden geen verschil in totaalscore voor patiëntgerichte zorg tussen T0 en T1, wat suggereert dat audit en feedback alleen niet genoeg zijn om de patiëntgerichtheid van de fertiliteitszorg te verbeteren. De resultaten van de interviews lieten zien dat de motivatie van professionals om te verbeteren en de kennis om feedback om te zetten in een adequaat verbeterprogramma niet optimaal waren. Dit lijken dan ook de belangrijkste aanknopingspunten te zijn om tot een succesvol verbeterprogramma voor patiëntgerichte fertiliteitszorg te komen.

Hoofdstuk 8

Het vorige hoofdstuk heeft ons belangrijke informatie opgeleverd over de samenstelling van een optimaal verbeterprogramma voor patiëntgerichte fertiliteitszorg. Gebaseerd op deze bevindingen en overige literatuur over patiëntgerichte zorg ontwierpen wij een studie om het effect van een *multifaceted* interventie strategie op de patiëntgerichtheid van de zorg te bepalen. In dit hoofdstuk beschrijven we het studie protocol van deze studie. In een clustergerandomiseerde studie in 32 Nederlandse ziekenhuizen zal het effect van de *multifaceted* interventie op de patiëntgerichtheid worden bepaald, zoals gemeten met de PCQ-Infertility vragenlijst. Ook het effect op de kwaliteit van leven van patiënten (FertiQoL vragenlijst) en stress (SCREENIVF vragenlijst) zal bepaald worden. In totaal zullen 16 klinieken gerandomiseerd worden voor de interventie, bestaande uit 3 onderdelen. Allereerst ontvangen deze klinieken een persoonlijk feedbackrapport met de resultaten van het vragenlijstonderzoek gepresenteerd in relatie tot de resultaten van de overige ziekenhuizen. Dit rapport zal vervolgens per ziekenhuis in een educatieve bijeenkomst met het hele fertiliteitsteam besproken worden, waaruit enkele concrete actiepunten ter verbetering van de patiëntgerichtheid ontstaan waar het team een jaar lang aan zal werken. Daarnaast worden teams aangemoedigd de communicatie tussen professionals en patiënten verder te optimaliseren, bijvoorbeeld door het organiseren van focusgroepen. De 16 klinieken in de controlegroep leveren zorg als voorheen. Na een jaar zal het vragenlijstonderzoek worden herhaald. We verwachten met de resultaten van deze studie nieuwe en belangrijke aanwijzingen te verzamelen over het verbeteren van de patiëntgerichtheid van de Nederlandse fertiliteitszorg. Bovendien kunnen deze resultaten als voorbeeld dienen voor vergelijkbare initiatieven in andere landen of andere specialismen.

Hoofdstuk 9

In dit hoofdstuk wordt het effect van de *multifaceted* interventie, zoals gepresenteerd in het vorige hoofdstuk, op de mate van patiëntgerichte fertiliteitszorg beschreven. Met behulp van multilevel multivariate lineaire regressie analyse berekenden we

het effect van de interventie op de totaal- en subscores van de PCQ-Infertility vragenlijst. Ook bepaalden we in welke mate patiëntkarakteristieken het effect van de interventie op de PCQ-Infertility totaalscores beïnvloedden door interactietermen op te nemen in de analyses. Tot slot werden de totale kosten die gepaard gingen met de uitvoer van de interventie bepaald. Tijdens de voormeting vulden 696 patiënten (respons 58.4%) uit 32 verschillende ziekenhuizen de vragenlijsten. Een jaar later, tijdens de nameting, hadden we de beschikking over data van 730 patiënten (respons 60.4%). De PCQ-Infertility totaalscores bleken niet significant verschillend tussen patiënten uit de interventie- en controlegroep in de nameting, waarbij we corrigeerden voor de resultaten uit de voormeting en voor meerdere relevante achtergrondkarakteristieken (bijv. leeftijd en soort behandeling). Op één van de zeven subschalen (continuïteit van zorg) werd echter wel een significant hogere en dus betere score in de interventiegroep behaald ($B=0.20$). Bovendien bleek dat de totaalscores in de interventiegroep significant hoger waren dan in de controlegroep als patiënten korter dan een jaar onder behandeling waren, jonger dan 36 jaar waren en als patiënten alternatieve zorg ontvingen. In totaal kostte de uitvoer van de interventie €64.628 per jaar, wat overeenkomt met €13 (range €2-€28) per patiënt per kliniek per jaar. Overige kosten (productieverlies en overige gezondheidszorgkosten) verschilden niet tussen de controle- en de interventiegroep. Deze resultaten laten zien dat feedback en educatie op basis van patiëntervaringen niet voldoende is om de patiëntgerichtheid van de fertiliteitszorg voor alle subfertiele patiënten te verbeteren. Verbetering voor bepaalde subgroepen was echter wel haalbaar. Dit suggereert dat toekomstig onderzoek zich op meer individuele strategieën en uitkomstmaten moet richten om de zorgervaringen van alle patiënten te kunnen verbeteren.

Hoofdstuk 10

Wanneer je het effect van complexe interventies bestudeert, is een uitgebreide procesevaluatie van de studie van groot belang. Procesevaluaties zijn namelijk niet geïnteresseerd in het (gebrek aan) succes van een studie, maar bekijken de interventie in meer detail om te zien wat er nu werkelijk is gebeurd om zo de studieresultaten beter te kunnen interpreteren. In hoofdstuk 10 beschrijven we de resultaten van een procesevaluatie van onze clustergerandomiseerde studie. Daarin evalueerden we de ervaringen van professionals en patiënten met de studie en bestudeerden we de relatie tussen de intensiteit waarmee de interventie werd uitgevoerd en de verbetering in patiëntgerichtheid scores. Tot slot analyseerden we de associatie tussen verschillende kliniekkarakteristieken en een toename in patiëntgerichtheid. We hebben verschillende vragenlijsten gebruikt om onze data te verzamelen en constateerden dat zowel patiënten als professionals grotendeels positief waren over de verschillende onderdelen van de interventie. Tijdens de

educatieve bijeenkomst werden er vijf actiepunten per kliniek opgesteld om hun patiëntgerichtheid te verbeteren (mediaan, range: 3-7). Na één jaar waren 75% van deze actiepunten werkelijk uitgevoerd (range: 20-100%). Zowel de interventie- als controleklinieken werkten echter ook aan andere, extra actiepunten tijdens de studie. Lineaire regressieanalyses liet zien dat het aantal verbeterprojecten per kliniek (actiepunten en extra verbeterprojecten) niet gerelateerd was aan een verbetering in patiëntgerichtheid scores. Multivariate regressie analyse toonde dat verbetering van patiëntgerichtheid wel geassocieerd was met een hogere mate van patiëntparticipatie tijdens de educatieve bijeenkomsten, een hogere groeps cultuur score van een kliniek en de afwezigheid van wekelijks, gestructureerde patiëntbesprekingen voor het fertiliteitsteam. Patiëntparticipatie, teamwerk en een verminderde fixatie op protocollen en richtlijnen kunnen daarom als belangrijke elementen worden gezien om de patiëntgerichtheid in de dagelijkse praktijk werkelijk te verbeteren.

Hoofdstuk 11

Dit hoofdstuk beschrijft de **Algemene Discussie** van dit proefschrift, waarin de belangrijkste bevindingen worden samengevat en besproken. We geven antwoord op de acht onderzoeksvragen die in de Algemene Introductie werden gesteld en bespreken deze bevindingen door allereerst op het concept 'patiëntgerichtheid' in te gaan. Het bestuderen van patiëntgerichtheid van de zorg kan in onze ogen beschouwd worden als een zogenaamde 'alpha' wetenschap, aangezien het sterk afhankelijk is van de individuele context van de patiënt. Studies die zich bijvoorbeeld op de effectiviteit of veiligheid van de zorg richten kunnen daarentegen als 'beta' wetenschappen worden bestempeld; vaste uitkomstmaten die grotendeels onafhankelijk zijn van hun context. Door deze verschillen zou het meten en verbeteren van patiëntgerichte zorg op een andere manier moeten worden benaderd dan andere dimensies van kwaliteit van zorg. Waarschijnlijk is hier een belangrijk rol weggelegd voor de psychosociale situatie van de patiënt, vooral omdat in meerdere vakgebieden in de gezondheidszorg een relatie tussen patiëntgerichte zorg en de psychosociale gezondheid van de patiënt wordt gezien. In de fertiliteitszorg is de richting van deze relatie echter nog onduidelijk en ook enkel onderzocht bij de vrouw, terwijl ook partners een belangrijk onderdeel van het subfertiele paar zijn. Het is duidelijk dat meer onderzoek op dit gebied nodig is. Vervolgens wordt besproken dat patiëntgerichtheid van de zorg nog steeds met vragenlijsten worden gemeten die zich richten op de gemiddelde patiënt in plaats van op de individuele patiënt met zijn eigen verwachtingen, wensen en ideeën. Voor de toekomst adviseren we om de patiëntgerichtheid van de zorg dan ook op zowel ziekenhuis- als individueel niveau te meten en verbeteren. The

PCQ-Infertility vragenlijst kan hiervoor worden gebruikt om op ziekenhuisniveau verbeterpunten vast te stellen, die vervolgens met het gehele team besproken en verbeterd kunnen worden. Daarnaast is het van belang dat zorgverleners de normen, waarden en verwachtingen van de individuele patiënt in het oog houden door deze aan het begin van de behandeling te bespreken en samen te vatten in een behandelplan. Dit plan kan door het gehele behandeltraject als een gids voor zowel zorgverlener als patiënt worden gebruikt. Ten slotte benadrukken we dat gerandomiseerde studies nog steeds de gouden standaard zijn voor studies die context-onafhankelijke, 'beta' wetenschappen bestuderen. Voor 'alpha' wetenschappen zoals patiëntgerichtheid zouden mixed-method studies, kwalitatieve of meer pragmatische studies wellicht meer van bruikbaar zijn. We eindigen onze Algemene Discussie met onze aanbevelingen voor patiënten, zorgverleners, beleidsmakers en toekomstig onderzoek.

APPENDICES

PCQ-INFERTILITY QUESTIONNAIRE

PHD THESES HUMAN REPRODUCTION

BIBLIOGRAPHY

DANKWOORD

CURRICULUM VITAE

Patient-Centredness Questionnaire-Infertility

PCQ-Infertility

Questionnaire on Couples' Experiences with Fertility Care

This questionnaire is intended for patients receiving treatment for fertility problems.

This questionnaire was developed by the research team Reproductive Medicine of the Radboud University Nijmegen Medical Centre in cooperation with the Erasmus Medical Centre in Rotterdam and the Isala Clinics in Zwolle.

Information about the questionnaire

This 51-item questionnaire includes 4 background questions and 47 'experience' questions. These questions concern the way you and your spouse have experienced the fertility care in your hospital during the past twelve months.

There are no "right" or "wrong" answers. Your views and experiences are what matters. Please do not think too long before answering each question. Your first answer usually is the best answer.

Explanation of differences in terminology

"The physician" indicates only gynaecologists and/or fertility specialists who are treating you or who have treated you.

"Caregivers" include physicians as well as nurses.

"Staff" includes all staff members you saw at the department, ranging from physicians and nurses to laboratory workers and personnel at the reception.

"The treatment period" indicates the entire period of time including both the diagnostic and treatment phase.

Explanation of possible answers

If a question can be answered as indicated below, the answer has the following meaning:

'never'	= the situation in question never occurred or did not occur in 9 out of 10 cases
'sometimes'	= the situation in question occurred in about 1 out of 3 cases
'usually'	= the situation in question occurred in about 3 out of 4 cases
'always'	= the situation in question occurred always or in 9 out of 10 cases.

Certain questions may not apply, or you may not have experienced certain aspects of the treatment. In that case, please answer the question with "does not apply". If possible, please answer the questions together with your spouse.

Although some questions may appear to be similar to each other, it is important for the improvement of fertility care that you fill in the questionnaire *completely* and that you do not omit any questions.

Please answer the questions by marking them with an X in the little square that is printed at the left of your answer.

It will take you 10-15 minutes to complete the questionnaire.

Background questions

The questions below are about you and your treatment

1. About which hospital are you filling in this questionnaire?

.....

2. What is the highest level of education you completed?

- ☐ None
- ☐ Primary or lower vocational education
- ☐ Secondary or intermediate vocational education
- ☐ Higher professional education or University
- ☐ Other

3. What treatment are you receiving or did you receive recently?

Only one answer possible

- ☐ No treatment has been initiated yet
- ☐ Ovulation induction (stimulating ovulation with hormones)
- ☐ Intrauterine insemination (either with or without any hormone stimulation)
- ☐ IVF or ICSI (test-tube fertilization)
- ☐ Other

4. Are you pregnant at this moment?

- ☐ No
- ☐ Yes

Accessibility

The questions below are about the attainableness of your treating team (by telephone)

1. **How often have you been able to speak to someone immediately when you called the Fertility Department?**
 - ☐ Never
 - ☐ Sometimes
 - ☐ Usually
 - ☐ Always
2. **Was it a problem for you to contact staff (by telephone or e-mail) if you had any questions?**
 - ☐ A great problem
 - ☐ A minor problem
 - ☐ No problem
 - ☐ Does not apply; I never tried to contact any staff

Information and explanation

The questions below are about the information and explanation you received during your treatment

3. **Did you receive contact numbers for urgent questions or problems at nights or weekends?**
 - ☐ No
 - ☐ Yes
4. **Did you also receive written information apart from verbal information?**
 - ☐ No
 - ☐ Yes, but insufficient information
 - ☐ Yes, absolutely
5. **Was the information about the investigations you would undergo comprehensive?**
 - ☐ No, not at all
 - ☐ Somewhat
 - ☐ For the most part
 - ☐ Yes, absolutely

6. Were different treatment options discussed with you?

- ☐ No
- ☐ Yes, but insufficiently
- ☐ Yes, absolutely

7. Was the information about the treatment you would receive comprehensive?

- ☐ No, not at all
- ☐ Somewhat
- ☐ For the most part
- ☐ Yes, absolutely

8. Did you receive an overview of your treatment plan with a time schedule?

- ☐ No
- ☐ Yes

9. Were you informed of any possible side-effects of the medication prescribed to you?

- ☐ No
- ☐ Yes, but insufficiently
- ☐ Yes, absolutely
- ☐ Does not apply; no medication was prescribed to me

10. Were the instructions on how to inject your hormones comprehensive?

- ☐ No, not at all
- ☐ Somewhat
- ☐ For the most part
- ☐ Yes, absolutely
- ☐ Does not apply

11. Did the staff inform you how to get support from a social worker or a psychologist?

- ☐ No
- ☐ Yes, but insufficiently
- ☐ Yes, absolutely

12. Did you miss any instructions from a nurse? If so, when?

More than one answer possible

- ☐ During the first consultation (intake)
- ☐ With new medication
- ☐ After you received a treatment plan
- ☐ Before or after a puncture
- ☐ Before or after an embryo transfer
- ☐ Before or after a pregnancy test
- ☐ I did not miss any instructions

13. Were there any periodical evaluations to overlook your treatment period?

- ☐ No
- ☐ Yes, but insufficient talks
- ☐ Yes, absolutely
- ☐ I have only just begun treatment or did not begin any treatment yet

Staff's communication skills

The questions below are about how the team communicated with you

14. Were caregivers honest and clear about what to expect from the fertility care service?

e.g. about your success rates and possibilities

- ☐ No, not at all
- ☐ Somewhat
- ☐ For the most part
- ☐ Yes, absolutely

15. Were the results of the investigations discussed with you?

- ☐ No
- ☐ Yes, but insufficiently
- ☐ Yes, absolutely

16. How often did the physician listen to you carefully?

- ☐ Never
- ☐ Sometimes
- ☐ Usually
- ☐ Always

17. How often did the physician take you seriously?

- ☐ Never
- ☐ Sometimes
- ☐ Usually
- ☐ Always

18. How often did the physician take the time for you?

- ☐ Never
- ☐ Sometimes
- ☐ Usually
- ☐ Always

19. How often did you have the impression that staff was talking "about" you instead of talking to you?

- ☐ Never
- ☐ Sometimes
- ☐ Usually
- ☐ Always

20. Was staff willing to talk to you about errors or incidents?

- ☐ No
- ☐ Yes
- ☐ Does not apply; nothing went wrong

Involvement in your treatment

The questions below are about the extent of your involvement in treatment

21. How often was your physician open to your opinion and ideas about treatment?

- ☐ Never
- ☐ Sometimes
- ☐ Usually
- ☐ Always

22. How often were you given the opportunity to ask your physician questions?

- ☐ Never
- ☐ Sometimes
- ☐ Usually
- ☐ Always

23. Was decision-making shared with you, if you preferred?

- ☐ No, not at all
- ☐ Somewhat
- ☐ For the most part
- ☐ Yes, absolutely

Respect for your values and needs

The questions below are about how you were cared for during your treatment and whether the team showed an interest in you

24. Did you have access to your own medical record during the treatment period?

- ☐ No, none at all
- ☐ Yes, but insufficient access
- ☐ Yes, absolutely
- ☐ I do not know

25. How often did your physician show an interest in your personal situation?

- ☐ Never
- ☐ Sometimes
- ☐ Usually
- ☐ Always

26. How often did your physician have empathy for your emotions and your current situation?

- ☐ Never
- ☐ Sometimes
- ☐ Usually
- ☐ Always

27. Did nurses show understanding for your situation?

- ☐ No, none at all
- ☐ Some
- ☐ Much
- ☐ Yes, absolutely

28. Did staff also involve your partner?

- ☐ No, none at all
- ☐ Some
- ☐ Much
- ☐ Yes, absolutely
- ☐ No, my partner never accompanied me

29. How often did you receive any personal attention and support from nurses during your treatment?

- ☐ Never
- ☐ Sometimes
- ☐ Usually
- ☐ Always

30. Did staff pay attention to any possible emotional impact of fertility problems?

- ☐ No, none at all
- ☐ Some
- ☐ Much
- ☐ Yes, absolutely
- ☐ Does not apply / I do not know

Continuity and transition during your treatment

The questions below are about uniformity within your care and cooperation between care givers

31. Was one staff member assigned to you to contact any time you had any questions or problems (e.g. a nurse)?

- ☐ No
- ☐ Yes

- 32. How many different physicians are or were involved in your treatment at your present hospital?**
- ☐ 1 or 2
 - ☐ 3 or 4
 - ☐ 5 or more
- 33. Did you have one lead physician (a physician for moments of evaluation and decision-making)?**
- ☐ No lead physician was assigned to me
 - ☐ Yes, but I saw him or her too little
 - ☐ Yes, absolutely
- 34. How often did you have an appointment with the same physician?**
- ☐ Never
 - ☐ Sometimes
 - ☐ Usually
 - ☐ Always
- 35. How often did you have to repeat the same story to different physicians?**
- ☐ Never
 - ☐ Sometimes
 - ☐ Usually
 - ☐ Always
- 36. How often did you get contradictory information or advice?**
- ☐ Never
 - ☐ Sometimes
 - ☐ Usually
 - ☐ Always

37. Did caregivers contradict each other in policy (one says one thing, the other says something else)?

- ☐ No, not at all
- ☐ Somewhat
- ☐ For the most part
- ☐ Yes, absolutely

Staff's competence

The questions below are about how skilled and competent the staff appeared to you

38. How often did staff use difficult words without explaining them to you?

- ☐ Never
- ☐ Sometimes
- ☐ Usually
- ☐ Always

39. How often was your physician well prepared for an appointment?

- ☐ Never
- ☐ Sometimes
- ☐ Usually
- ☐ Always

40. Did the physician(s) seem competent to you?

- ☐ No, not at all
- ☐ Somewhat
- ☐ For the most part
- ☐ Yes, absolutely

41. How often did staff work disorderly?

- ☐ Never
- ☐ Sometimes
- ☐ Usually
- ☐ Always

42. How often were logistics smooth at the Fertility Department?

- ☐ Never
- ☐ Sometimes
- ☐ Usually
- ☐ Always

43. How long did you usually have to wait in the waiting room?

- ☐ More than 1 hour
- ☐ 30 to 60 minutes
- ☐ 15 to 30 minutes
- ☐ Less than 15 minutes

Care organisation

The questions below are about how much time it took you to finish your treatment

44. How often did you have to wait more than 3 weeks if you wanted to make an appointment with the physician?

- ☐ Never
- ☐ Sometimes
- ☐ Usually
- ☐ Always

45. How much time passed between your first hospital visit and the moment you received your treatment plan?

- ☐ More than 6 months
- ☐ 4 to 6 months
- ☐ 2 to 4 months
- ☐ Less than 2 months

46. How long on average did you have to wait 'unnecessarily' before being able to start with a next treatment?

For example due to a waiting list or a summer break.

- ☐ More than 2 months
- ☐ 2 months
- ☐ 1 month
- ☐ I always was able to start directly with the next treatment
- ☐ Does not apply

In conclusion

47. What mark do you give the total fertility care at your hospital?

0 means extremely bad. 10 means excellent.

- ☐ 0 Extremely bad care
- ☐ 1
- ☐ 2
- ☐ 3
- ☐ 4
- ☐ 5
- ☐ 6
- ☐ 7
- ☐ 8
- ☐ 9
- ☐ 10 Excellent care

Room for additional remarks.

You have reached the end of the questionnaire.

If you have any remarks or comments you want to make about the care you received or about this questionnaire, please write them down below.
These data will be processed anonymously.

End of this questionnaire

Thank you very much for completing the questionnaire

MANUAL Patient-Centredness Questionnaire-Infertility

This section provides information on some practical issues when applying the PCQ for measuring the level of patient-centredness of your clinic.

How to convert item responses for scoring purposes:

4-answer categories:

- Never = 0; Sometimes = 1; Usually = 2; Always = 3
- No, not at all = 0; Somewhat = 1; For the most part = 2; Yes, absolutely = 3
- No, none at all = 0; Little = 1; Much = 2; Yes, absolutely = 3
- More than 1 hour = 0; 30 to 60 min = 1; 15 to 30 min = 2; less than 15 min = 3
- More than 6 months = 0; 4 to 6 months = 1; 2 to 4 months = 2; Less than 2 months = 3
- More than 2 months = 0; 2 months = 1; 1 month = 2; Start directly = 3

3-answer categories:

- A great problem = 0; A minor problem = 1; No problem = 3
- No = 0; Yes, but insufficiently = 1; Yes, absolutely = 3
- 1 or 2 = 3; 3 or 4 = 1 ; 5 or more = 0
- No = 0; Yes, but I saw him too little = 1; Yes, absolutely = 3

2-answer categories:

- No = 0; Yes = 3

Pay special attention to:

- Item 12: Instructions are missed for at least 1 answer category=0.
 No instructions missed=3
- Items 19, 35, 36, 37, 38, 41 and 44 need to be mirrored before scoring the question

The 7 dimensions of the PCQ-Infertility with accompanying items

Accessibility: 1 and 2
 Information: 3 through 13
 Communication: 14 through 20
 Patient involvement: 21 through 23
 Respect for patient's values: 24 through 30
 Continuity and transition: 31 through 37
 Competence: 38 through 43

The answer category "is not applicable" cannot be used when calculating means

Calculating 'mean dimension score' of patient-centredness

For calculating a mean dimension score, a participant's responses to the individual items within a dimension need to be summed up and divided the number of items filled in. To calculate a reliable score, *more than half* of the items within a dimension need to be completed.

Quality Improvement scores (QI scores)

To calculate QI-scores you can add per experience item an extra question to reveal the patient's importance regarding that specific care aspect.

For example:

Experience item: *How often did the physician take you seriously?*

Importance item: *How important did you find it that the physician takes you seriously?*

Answer categories: Extremely important = 3; Important = 2; fairly important = 1; not important = 0

To compute an improvement score per item the following formula can be used:

$$QI = I \times (3 - E)$$

I = mean importance score of your patients on this item

E = mean experience score of your patients on this item

Case-mix factors

When the PCQ-Infertility is used to benchmark clinics on patient-centredness, adjustment for (e.g. by using GLM in SPSS) or stratification on 3 significant background characteristics is recommended: (1) women's level of education, (2) current treatment, and (3) actual pregnancy. These characteristics appeared significantly associated with one or more subscales of patient-centredness. However, when more socio-demographic information is preferred, users are free to add more background questions to the questionnaire.

PhD theses Human Reproduction NCEBP (2000 – 2013)

2000

1. 07-02-2000 *Els van der Molen*
Disturbed homocysteine metabolism endothelial dysfunction and placental vasculopathy
2. 29-06-2000 *Willianne Nelen*
Risk factors for recurrent early pregnancy loss. Hyperhomocysteinaemia, thrombophilia and impaired detoxification
3. 05-09-2000 *Ina Beerendonk*
Sodium and ovarian hyperstimulation. Some clinical and psychological aspects
4. 04-12-2000 *Anne-Marie van Cappellen van Walsum*
Cerebral metabolism of hypoxic fetal sheep by NMR spectroscopy
5. 18-12-2000 *Friso Delemarre*
Vascular aspects of human pregnancy. Clinical studies on sodium restriction and angiotensin infusion

2001

6. 10-01-2001 *Way Yee Wong*
Male factor subfertility. The impact of lifestyle and nutritional factors
7. 05-06-2001 *Petra Zusterzeel*
Biotransformation enzymes and oxidative stress in preeclampsia
8. 05-10-2001 *Cathelijne van Heteren*
Development of habituation and memory in the human fetus
9. 10-10-2001 *Michael Gaytant*
Cytomegalovirus and herpes simplex virus infections in pregnancy

2002

10. 25-01-2002 *Ron van Golde*
Male subfertility and genetics
11. 21-05-2002 *Tanja de Galan-Roosen*
Perinatal Mortality

2003

12. 08-01-2003 *Maarten Raijmakers*
Oxidative stress and detoxification in reproduction with emphasis on glutathione and preeclampsia
13. 18-2-2003 *Sabine de Weerd*
Preconception counselling. Screening & periconceptual health
14. 22-4-2003 *Iris van Rooij*
Etiology of orofacial clefts. Gene-environment interactions and folate
15. 17-12-2003 *Chris Verhaak*
Emotional impact of unsuccessful fertility treatment in women

2004

16. 14-01-2004 *Liliana Ramos*
The quality of epididymal sperm in azoospermia
17. 04-10-2004 *Pascal Groenen*
Nutritional and environmental factors in human spina bifida. An emphasis on myo-inositol
18. 24-11-2004 *Tanya Bisseling*
Placental function in maternal disease. Ex vivo assessment of foetoplacental vascular function and transport in diabetes and preeclampsia
19. 15-12-2004 *Eva Maria Roes*
Oxidant-antioxidant balance and maternal health in preeclampsia and HELLP syndrome

2005

20. 01-06-2005 *Marieke Rijnsaardt-Lukassen*
Single Embryo Transfer: clinical and immunological aspects
21. 10-11-2005 *Ingrid Krapels*
The etiology of orofacial clefts. An emphasis on lifestyle and nutrition other than folate

2006

22. 14-06-2006 *Reini Bretveld*
Fertility among greenhouse workers
23. 09-11-2006 *Jesper Smeenk*
Stress and IVF. Clinical consequences

2007

24. 08-02-2007 *Inge Ebisch*
Human subfertility: explorative studies on some pathophysiologic factors in semen and follicular fluid
25. 01-11-2007 *Alwin Derijck*
The transmission of chromatin and DNA lesions by sperm and their fate in de zygote (1)
26. 01-11-2007 *Godfried van der Heijden*
The transmission of chromatin and DNA lesions by sperm and their fate in de zygote (2)
27. 03-12-2007 *Kirsten Kluivers*
On the measurement of recovery following hysterectomy
28. 10-12-2007 *Rene Kok*
Proton Magnetic Resonance Spectroscopy of Human fetal brain

2008

29. 10-12-2008 *Trudie Gerrits*

Clinical encounters: Dynamics of patient-centred practices in a Dutch fertility clinic

30. 12-12-2008 *Wouter Tuil*

IVF and Internet

2009

31. 06-03-2009 *Ineke Krabbendam*

Venous reserve capacity & autonomic function in formerly preeclamptic women

32. 03-09-2009 *Arno van Peperstraten*

Implementation of single embryo transfer

33. 07-10-2009 *Wilson Farid Abdo*

Parkinsonism: possible solutions to a diagnostic challenge

2010

34. 10-03-2010 *Suzan Broekhuis*

Dynamic MR imaging in female pelvic floor disorders

35. 12-03-2010 *Bea Lintsen*

IVF in the Netherlands: success rates, lifestyle, psychological factors and costs

36. 21-04-2010 *Selma Mourad*

Improving fertility care: the role of guidelines, quality indicators and patients

2011

37. 24-02-2011 *Monique Brandes*
Observational studies in reproductive medicine
38. 04-04-2011 *Marijn Brouwers*
Why foetal development of the male reproductive structures sometimes fails. An epidemiologic study on hypospadias and undescended testis with a focus on endocrine disruptors.
39. 22-06-2011 *Marian Spath*
Risk estimate for fragile X-associated primary ovarian insufficiency: Genetic, environmental and reproductive factors
40. 30-06-2011 *Inge van Empel*
Patient-centredness in fertility care
41. 18-11-2011 *Gwendolyn Woldringh*
ICSI children. Follow-up after ICSI with ejaculated or non-ejaculated sperm
42. 17-06-2011 *Tiny de Boer*
Aspects of surgery for pelvic organ prolapse and its relation to overactive bladder symptoms

2012

43. 20-01-2012 *Esther Haagen*
Guidelines in IUI care. Implications for quality improvement
44. 17-02-2012 *Loes van der Zanden*
Aetiology of hypospadias. From genes to environment and back
45. 11-04-2012 *Reda Z Mahfouz*
Oxidative stress and apoptotic biomarkers in human semen
46. 06-06-2012 *Marleen van Gelder*
The role of medical and illicit drug use in the etiology of birth defects. Epidemiological studies and methodological considerations.
47. 12-09-2012 *Annemijn Aarts*
Personalized fertility care in the Internet era

48. 17-09-2012 *Eline Dancet*

Bridging the gap between evidence based and patient-centred infertility and endometriosis care in Europe

49. 09-10-2012 *Berto Nieboer*

Minimally invasive surgery: patients and doctors perspectives.

50. 25-10-2012 *Sanne van Leijsen*

The value of urodynamics prior to surgery for stress urinary incontinence

51. 21-12-2012 *Marieke de Vries*

A cytological exploration of human spermatogenesis in non-obstructive azoospermia patients: an analysis of variation

2013

52. 16-01-2013 *Jacqueline Pieters*

Incidental Findings of Sex Chromosomal Aneuploidies in Routine Prenatal Diagnostic Procedures

53. 04-09-2013 *Ellen Lensen*

Surgery for pelvic organs prolapse with emphasis on the anterior compartment

54. 16-12-2013 *Renne Gerritse*

Cryopreservation of an intact ovary

2014

55. 23-01-2014 *Dana Huppelschoten*

Improving patient-centredness of fertility care

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Dankwoord

Ik ben ontzettend trots op dit proefschrift waar ik afgelopen paar jaren mijn ziel en zaligheid in heb gestopt. Nog trotser ben ik echter op het feit dat ik dit traject met zoveel slimme, kritische, maar vooral leuke mensen heb mogen doorlopen. Een aantal van hen wil ik hier graag in het bijzonder bedanken.

Het dankwoord van een proefschrift over patiëntgerichtheid kan uiteraard enkel starten met het danken van alle patiënten die hun steentje hebben bijgedragen. Daarbij noem ik de paar duizend patiënten die al mijn verschillende vragenlijsten hebben ingevuld, maar ook de (oud)-patiënten die zo dapper waren om de groepsbijeenkomsten bij te wonen en hun mening over (het verbeteren van) de patiëntgerichtheid van hun eigen fertiliteitsafdeling te geven. Ook de prachtige bijdrage van Ingrid aan dit proefschrift, het schrijven van de proloog, mag niet onbenoemd blijven. Mijn proefschrift had niet mooier kunnen beginnen, dank daarvoor!

Prof. dr. J.A.M. Kremer, beste Jan, een meer inspirerende promotor had ik me niet kunnen wensen. Ik vond de eerste gesprekken met jou erg spannend, maar ik ontdekte al snel dat deze meetings bedoeld waren om me een bredere kijk op de gezondheidszorg te geven en me aan te moedigen om weer voortvarend aan de slag te gaan. Ik kreeg veel vrijheid, maar kon ook altijd bij je terecht als ik het spoor even bijster was. Dank daarvoor, maar ook voor je onuitputtelijke positiviteit en vertrouwen in ons promotietraject.

Dr. W.L.D.M. Nelen, beste Willianne, als mijn enige co-promotor maakte je het team compleet en wat was ik blij met jou! Niet alleen je kritische houding, praktische en inhoudelijke kennis en je zeer nauwkeurige revisies waren van onschatbare waarde. Ook je gezelligheid bij de verschillende etentjes, uitjes en congressen heb ik zeer gewaardeerd. Dank voor al je hulp in de afgelopen jaren!

Ook alle medeauteurs van de verschillende artikelen wil ik danken voor hun bijdrage. Chris Verhaak en Angelique van Dongen, jullie hulp bij de meer psychologisch ingestoken artikelen was van grote waarde. Hetzelfde geldt voor de artikelen op het economische vlak, waar ik zonder de visie van Eddy Adang en de geniale statistiekuurtjes met Hans Groenewoud nooit uit was gekomen.

Uiteraard wil ik ook veel dank uitspreken naar de 32 fertiliteitsteams die met veel enthousiasme deelnamen aan mijn studie. Mijn dank gaat uit naar de gynaecologen en fertiliteitsartsen die de kar trokken in de verschillende klinieken, maar ook naar de verpleegkundigen, doktersassistenten, secretaresses, psychologen en kwaliteitsfunctionarissen die keer op keer weer met nieuwe plannen kwamen hoe we de patiëntgerichtheid in hun kliniek nog verder konden verbeteren. Zonder

jullie inzet had deze studie nooit kunnen bestaan!

Beste Eva, jouw enorme hulp als student verdient zonder meer een benoeming in mijn dankwoord. Hoe leuk was het om samen naar Londen te gaan om over 'ons' artikel te spreken en als uitsmijter mocht ik je enkele maanden geleden zelfs toespreken bij je afstuderen. Ik wens je alle succes voor de toekomst!

Beste (oud)-onderzoekers uit de kantoortuin, dank voor alle gezellige, ontspannende momenten die voor een fijne afwisseling zorgden tussen het harde werken door. Tom, wat fijn dat jij voor wat mannelijke input in 'onze vpg-hoek' zorgde, al was je er maar enkele dagen per week. Het is een ontzettende eer dat ik in februari jouw paranimf mag zijn! Inge en Annemijn, jullie hebben de tuin allang verlaten, maar toch wil ik jullie hier extra bedanken omdat jullie mij wegwijs hebben gemaakt in de wereld van de patiëntgerichte fertiliteitszorg. Ik vind het erg leuk dat ik nu jullie AIOS-collega mag zijn!

Ook wil ik dank uitspreken naar mijn oud-collega's uit het Jeroen Bosch Ziekenhuis in Den Bosch. De liefde voor de gynaecologie is bij jullie gestart en ik heb twee enorm fijne jaren bij jullie als ANIOS beleefd. Gelukkig mocht ik na mijn promotietraject het klinisch werk voortzetten in het Brabantse Land; in het Catharina ziekenhuis in Eindhoven voelde ik mij in oktober direct zeer welkom en ik weet zeker dat ik hier een ontzettend leerzame en gezellige opleidingstijd ga beleven.

Dan mijn vriendinnetjes: Eva, Marjan, Lianne, Lucie en natuurlijk alle 'heidies', het is top om zulke goede vriendinnen te hebben! Ik vond het erg fijn dat jullie zo geïnteresseerd waren in mijn onderzoek en de hoogtepunten met mij meevierden! En ja Eva, nu gaan we weer 'echt' aan het werk, ik ben alleen wel bang dat het ten koste zal gaan van onze tennisuurtjes ;-)

Lieve Marloes, het was direct duidelijk dat jij mijn paranimf moest zijn: mijn beste vriendin-colleegatje (en dan ook vooral in die volgorde!). Het klikte meteen toen jij in Den Bosch kwamen werken en ik maakte dan ook een vreugdedansje toen ik hoorde dat jij even later ook naar het Radboud kwam! Het ultieme doel is nu als opleidingsmaatjes verder, maar met jouw harde werken en mooie onderzoek moet dat helemaal goed komen. Dankjewel dat je tijdens mijn promotie naast me wil staan!

Lieve Fleur, ik ben ook heel blij dat jij mijn paranimf wilt zijn. De uitspraak: 'Beter een goede buur dan een verre vriend' is op ons wel van toepassing. Een betere en gezelligere 'overbuuf' had ik me namelijk niet kunnen wensen tijdens mijn laatste jaartjes in de kantoortuin. En dan bleek je ook nog eens met regelmaat in mijn straat in Den Bosch rond te hangen, aangezien mijn buurvrouw jouw

beste vriendin is! Ik wens ook jou heel veel succes met de laatste loodjes van je onderzoek en hoop dat we het Bourgondische leven in Den Bosch samen nog vaak in stand mogen houden!

Ook wil ik dank uitspreken naar mijn (schoon)familie voor wie het vaak maar abracadabra was waar Dana nou ook alweer mee bezig was. Toch waren jullie allemaal even geïnteresseerd als ik op een familiefeestje weer eens probeerde uit te leggen waar mijn onderzoek over ging.

Wilco, jij kreeg volgens mij pas echt besef van de omvang van een promotietraject toen je de uitdaging aanging om de cover en lay-out van mijn proefschrift te verzorgen. Maar wat heb je dat goed gedaan. Als dit een voorbode is voor je verdere werk dan gaat mijn 'kleine broertje' echt een goede architect worden!

Erica, ik ben ontzettend benieuwd wat jij van mijn proefschrift vindt, want aan jouw manier van schrijven kan ik natuurlijk niet tippen. Ik ben heel blij dat je het zo naar je zin hebt op je huidige werk en ik hoop dat je al je schrijf- en onderwijstalent in de komende jaren maximaal kunt inzetten.

Papa en Elly, jullie ook bedankt voor jullie morele steun tijdens mij promotieonderzoek. Wat fijn dat jullie speciaal voor deze gelegenheid terugkomen naar Nederland.

En dan mijn lieve mama, een grotere fan kan ik me niet wensen. De link naar Pubmed staat in je 'Favorieten' en mijn gepubliceerde artikelen hangen uitgeprint boven je bureau! Je bent de beste moeder die ik me kan wensen en ik weet zeker dat je apentrots op de eerste rij zit tijdens mijn verdediging! Ik ben je ontzettend dankbaar dat je mij alle kansen om te studeren en promoveren hebt kunnen en willen geven!!

Last but not least, mijn lieve Laurens, zonder jou had ik dit allemaal niet gekund. Al twaalf jaar mijn lief, maar ook mijn allerbeste maatje. Jij kent mij als geen ander en geeft mij alle ruimte om mijn droom om gynaecoloog te worden te verwezenlijken. Met jouw relativeringsvermogen en humor help je mij door mijn moeilijke momenten heen, waar ik je ontzettend dankbaar voor ben. Ik kijk enorm uit naar de rest van ons fijne leven samen!

Curriculum Vitae

Dana Huppelschoten werd op 10 augustus 1984 als oudste van drie kinderen geboren in het dorpje Hooglanderveen. Op 6-jarige leeftijd verhuisde zij met haar familie naar de polder, waar ze in Dronten en Kampen de basisschool en middelbare school doorliep. Dana wist al vroeg dat ze arts wilde worden. Gelukkig kon ze in 2002, na het behalen van haar VWO-diploma, direct starten met de opleiding Geneeskunde in Nijmegen.

Naast haar studie Geneeskunde volgde Dana vanaf 2003 een tweejarig traject aan de Radboud Honours Academy, een initiatief van de Radboud Universiteit om over de grenzen van de eigen studie te kijken. Ook was Dana actief binnen een commissie van de Medische Faculteit Vereniging Nijmegen (MFVN) en was zij bestuurslid van het Nijmeegse Studentenkor Alphonse Diepenbrock (NSKAD) in het jaar 2005-2006.

Tijdens het doorlopen van haar coschappen in 2007 en 2008 werd het Dana meer dan duidelijk dat ze gynaecoloog wilde worden. Om verder te komen in dit mooie specialisme volgde zij een keuze coschap binnen het vak en liep haar wetenschappelijke stage op de afdeling Voortplantingsgeneeskunde van het UMC St Radboud in Nijmegen. Tijdens deze stage werkte zij mee aan het promotieonderzoek van dr. Inge van Empel naar de ontwikkeling van de Patient-Centredness Questionnaire-Infertility, onder leiding van prof. dr. Jan Kremer.

Nadat Dana in 2009 haar artsenexamen behaalde, werkte zij twee jaar vol enthousiasme als ANIOS Gynaecologie in het Jeroen Bosch ziekenhuis te 's-Hertogenbosch. Tijdens haar eerdere stage was echter ook de nieuwsgierigheid naar het doen van wetenschappelijk onderzoek gewekt. Toen zich in 2011 de mogelijkheid aandeed om een promotieonderzoek te starten onder leiding van prof. dr. Jan Kremer en dr. Willianne Nelen, greep zij dit dan ook met twee handen aan, hetgeen binnen drie jaar resulteerde in dit proefschrift.

Dana is op 1 oktober 2013 gestart met haar opleiding tot gynaecoloog in het Catharina ziekenhuis te Eindhoven, bij opleider dr. Simone Kuppens.

Sinds 2001 heeft Dana een relatie met Laurens Schouten met wie ze sinds 2007 samenwoont in 's-Hertogenbosch.

